i-STAT
System Manual

Abbott - 323-9100
800 366-8020
6F2001 = 75^{00}

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Technical Service (800) 366-8020

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i-STAT
CORPORATION

Important!

i-STAT Portable Clinical Analyzer System Manual Update

As of July 18, 2001, the Portable Clinical Analyzer System Manual has been updated. Please **ADD** and **DELETE** the sheets as listed below. Once the updates have been completed these instructions may be discarded. If you have any questions about these instructions please contact your i-STAT support provider.

A ► ADD SHEET ◄ D DESTROY SHEET

Item	**Art#**	**Rev. Date**	
► CTI Sheet: Glucose	714177-00 A	06/11/01	✓
◄ CTI Sheet: Glucose	N/A	June 1998	✓
► CTI Sheet: PCO2/HCO3/TCO2/BE/AG	714182-00 B	07/05/01	✓
◄ CTI Sheet: PCO2/HCO3/TCO2/BE/AG	N/A	N/A	✓
► CTI Sheet: Creatinine	714183-00 A	06/05/01	✓
◄ CTI Sheet: Creatinine	N/A	N/A	
► CTI Sheet: Lactate	714184-00 A	06/08/01	✓
◄ CTI Sheet: Lactate	151642/Rev -	N/A	
◄ Propofol Interference Notice	US151617/Rev -	02/2001	
◄ Thiopental Sodium Interference Notice	US151618/Rev -	02/2001	
◄ Hydroxyurea Interference Notice	US151619/Rev -	02/2001	

END

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Important!

i-STAT System Manual Update

As of October 2001, the current i-STAT System Manual has been updated. Please **ADD** and **DELETE** the sheets as listed below. Once the updates have been completed these instructions may be discarded. If you have any questions about these instructions please contact your i-STAT support provider.

A ▶ ADD SHEET ◀ D DESTROY SHEET

	Item	Art#	
A▶	$P\text{CO}_2$ Cartridge and Test Information Sheet	714182-00C	✓
◀D	$P\text{CO}_2$ Cartridge and Test Information Sheet	714182-00B	✓
A▶	Technical Bulletin: October 2001 Update to i-STAT System Manual	714594-00A	✓
A▶	Technical Bulletin: i-STAT Celite ACT Heparin Linearity Procedure	714547-00A	
A▶	Technical Bulletin: Proficiency Testing on the i-STAT® System	714262-00B	✓
◀D	Technical Bulletin: Proficiency Testing on the i-STAT® System	All	✓

END

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CERAMIC CARTRIDGE USE LOG

Ceramic Cartridge Serial Number[1] ___________

NEW STRIP.
Check one box below each time an analyzer is ***repaired*** (i.e., for every 3 uses) with the ceramic cartridge (serial number shown above).
There are 100 boxes.
If the strip is damaged and replaced, start a new log.
After all the boxes immediately below are checked, rotate the strip as instructed and continue to check-off boxes for each analyzer repair.

FIRST ROTATION: Rotate the strip 180 degrees, keeping the same side up.
Check one box below each time an analyzer is ***repaired*** (i.e., for every 3 uses) with the ceramic cartridge (serial number shown above).
There are 100 boxes.
If the strip is damaged and replaced, start a new log.
After all the boxes immediately below are checked, rotate the strip as instructed and continue to check-off boxes for each analyzer repair.

SECOND ROTATION: Flip the strip over, so the bottom side is now up.
Check one box below each time an analyzer is ***repaired*** (i.e., for every 3 uses) with the ceramic cartridge (serial number shown above).
There are 100 boxes.
If the strip is damaged and replaced, start a new log.
After all the boxes immediately below are checked, rotate the strip as instructed and continue to check-off boxes for each analyzer repair.

THIRD AND LAST ROTATION: Rotate the strip 180 degrees, keeping the same side up.
Check one box below each time an analyzer is ***repaired*** (i.e., for every 3 uses) with the ceramic cartridge (serial number shown above).
There are 100 boxes.
If the strip is damaged and replaced, start a new log.
After all the boxes are checked, discard the strip as instructed below.

DISCARD STRIP. Replace the strip with a new strip, and start a new log.

---

[1] Serial Number is etched on the cartridge base.

i-STAT
CORPORATION

URGENT
i-STAT PRODUCT CORRECTION: WARNING LABELING

July 2001

Dear i-STAT User:

Enclosed please find additional important information and instructions as a follow-up to the recent interference notices sent to your facility at the end of February 2001 [dated February 26, 2001]. Those notices stated that the anesthetic drugs propofol and thiopental sodium can cause clinically significant errors in the i-STAT $P\mathrm{CO}_2$ test and that the anti-tumor drug hydroxyurea causes errors in the i-STAT tests for creatinine, glucose, and lactate.

That information has now been incorporated into Cartridge and Test Information (CTI) Sheets for each of these four i-STAT tests. Those revised CTI Sheets are included with this mailing. In addition, you are being provided with a label to be applied to each analyzer in your facility that will inform users of the potential for interfering substances including the three drugs mentioned above. This label together with the revised CTI Sheets will provide assurance that users are fully aware of the possibility that test results may be affected by interfering substances in patients' blood samples. At high concentrations of propofol and thiopental sodium an alternate method to assess $P\mathrm{CO}_2$ should be used as described in the CTI Sheet for $P\mathrm{CO}_2$.

i-STAT Corporation has voluntarily initiated these corrective actions and has informed the US Food and Drug Administration (FDA) of its actions. Although we are not removing any product from the market, this product correction is officially classified as a recall by FDA and is being conducted with the full knowledge and advisement of FDA. You will note that the revised CTI Sheet for $P\mathrm{CO}_2$ indicates that we are actively working to reduce the level of interference on this sensor. The FDA is currently reviewing our request for clearance to market (a "510(k)" submission) a version of software that provides this improvement. We will provide information about this improvement when it becomes available.

It is important that you follow the instructions and return the completed Acknowledgement Form to i-STAT Corporation as soon as possible.

Following is a list of items enclosed in this package.

Replace/rotate the ceramic strip if you suspect the ceramic cartridge is worn (e.g., over 100 uses) or the ceramic is dirty or contaminated (other than normal wear marks) and repeat the repair procedure. Otherwise, or if the QC Code 23 persists, contact your i-STAT support provider.

6) Update the Use Log to keep track of the number of repair uses of the ceramic cartridge.

Replacing/Rotating The Ceramic Strip

The ceramic strip is abrasive, and after repeated use, the abrasive surface wears-down and becomes less effective. The strip may be used to repair up to100 Analyzers before the strip must be rotated, or up to 400 Analyzers before the strip must be replaced, to ensure proper abrasiveness.

Procedure for rotating the strip:

1) Using a small Phillips head screwdriver, loosen and remove the screw and retainer.
2) Grip the ceramic strip with a plastic tweezers.
Note: The ceramic strip is brittle and should be handled with care, i.e., with plastic tweezers, to avoid damaging or contaminating it.
3) Inspect the ceramic strip for damage. Replace if cracked or chipped. CRACKED STRIPS MUST BE REPLACED BEFORE USING THE CERAMIC CARTRIDGE IN AN ANALYZER.
4) Inspect the aluminum base. Clean if necessary with isopropyl alcohol and soft, lint-free cloth. Avoid using paper that might leave fibers on the ceramic cartridge and carry them into the analyzer.
5) Rotate the ceramic strip to the next orientation (either spin around or flip over).
Note: The ceramic cartridge may be used to perform 100 repairs before rotating or replacing the strip. The strip may be rotated 3 times before replacing it (i.e., the strip has a total of 4 positions; original position of the strip plus 3 rotations). In other words, a single strip may be used to repair 400 analyzers – 100 analyzers per orientation of the strip. The 4 orientations are:

    1. Initial position,
    2. Rotate the strip by "spinning it" 180 degrees, same side up.
    3. Rotate the strip by turning it over, now back-side up.
    4. Rotate the strip by "spinning it" again 180 degrees, back-side still up.

6) Place the ceramic strip in the base, making sure it sits flat in the recess and does not overhang either edge (i.e., the inner edges adjacent to the strip, not the wider edges back on the body of the cartridge).
7) Replace the retainer plate and retainer screw.
Note: Over-tightening the screw may damage the threads in the base or crack the ceramic strip.
8) Record the strip rotation in the Use Log.

Procedure for replacing the strip:

1) Follow the same procedure as above, except discard the old strip and insert a new strip in its place.

6

Instructions For Using The Ceramic Cartridge

The following procedure repairs Analyzers that report excess number of Quality Check Code 23's, and in some instances, hematocrit "star-outs."

General Notes

The ceramic cartridge consists of an aluminum base that supports a ceramic "strip." The strip is a white strip of alumina that is held down by a brass retainer and retainer screw. The ceramic cartridge may be used up to 100 times before the strip is worn and needs to be rotated or up to 400 times before the strip must be replaced as described later in this guide.

Request replacement parts by contacting your i-STAT support provider and refer to the following i-STAT part numbers:

Description	Part Number
Ceramic Cartridge, Packaged (with box, spare strips, etc.)	014541-01
User Guide, Ceramic Cartridge	014540-01
Ceramic Cartridge (Cartridge only)	014499-01
Ceramic Strip	014542-01
Screw	014543-01
Retainer (brass plate with hole in it)	014544-01
Base (Aluminum support shaped like cartridge)	014545-01

Repairing The Analyzer

1) Check the Use Log for the ceramic cartridge. If the ceramic strip needs to be replaced or rotated (i.e., 100 uses since the last ceramic cartridge rotation/replacement), see instructions later in this procedure.

2) Inspect the ceramic cartridge for damage. Check to make sure the ceramic strip is centered (i.e., is not hanging over either edge), that the screw is secure, and that the ceramic is not chipped or cracked. Wear marks (appearing as small lines on the ceramic) are normal.

3) Run an external Electronic Simulator. If the analyzer does not PASS the external Electronic Simulator, contact your i-STAT support provider. Running the external Electronic Simulator ensures the *internal* Simulator cycle will not start during the repair cycle. If the internal simulator cycle starts, the error codes will result in the analyzer aborting the cycle before the repair is complete.

4) Run the ceramic cartridge 3 times. The instrument will identify the cartridge as an external Electronic Simulator. After each ceramic cartridge run, the analyzer will display a Simulator error code, i.e. "rRGL." Disregard all error messages. This is normal behavior.

5) Run 1 non-thermal cartridge. The Quality Check Code 23 should *not* occur. If the QC Code 23 occurs, repeat steps 2 and 4. If QC Code 23 persists, the ceramic strip may be worn or contaminated.

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i-STAT Exhibit A License Agreement

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Patents

CA 1,303,175; TW NI-36550; US 4,954,087; US Des. 332,833; TW NI-53285;
US 5,112,455; US 5,124,661; US 4,864,229; US 5,096,669; CA 1,281,072;
TW NI-41000; US 4,933,048; US 5,200,051; CA 1,342,975; US 5,008,616;
US Des. 337,164; US 5,212,050; CA 1,330,888; TW NI-65078; US 5,466,575
EP 0434742; JP 2113412; US 5,605,664; US 5,614,416; US 5,609,824; US 5,554,339;
US 5,514,253.

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INTRODUCTION

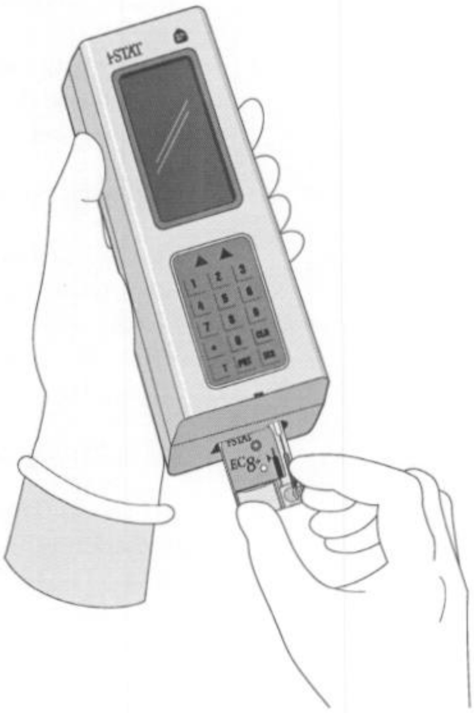
1

THE i-STAT SYSTEM

The i-STAT® System incorporates a comprehensive group of components needed to perform blood analysis at the point of care. Just 2–3 drops of fresh whole blood is all that is required, and a portable, battery-powered Analyzer or Hewlett-Packard patient monitor (with a Blood Analysis Module installed) displays quantitative test results in approximately 2 minutes. Portable printers and infrared communication devices allow all patient information obtained at the bedside to be printed on demand and transmitted to centralized information systems for recordkeeping and billing.

i-STAT System Components:

- Cartridges
- Handheld Analyzer
- Hewlett-Packard Blood Analysis Module
  (used in conjunction with a HP patient monitor)
- Portable Printer
- Quality Assurance Materials
    - Electronic Simulator
    - Control Solutions
    - Calibration Verification Set
- Central Data Station
    - IR Link
    - Computer
    - Printer
    - LIS/HIS Interface Software
    - - AME (terminal emulation interface)
    - - ASTM



The selection of system components is dependent on factors unique to each facility such as: number of testing sites, distance between testing sites, number of tests performed per site, number of operators to be certified to use the system, and recordkeeping requirements.

Note: *The i-STAT handheld analyzer and HP Blood Analysis Module essentially have the same features and perform the same basic functions, although some elements of the Blood Analysis Module's user interface have been appropriately adapted for a patient monitoring environment. In the interest of simplicity, when operating instructions or references apply to both pieces of equipment throughout this manual, they will be collectively referred to as "Analyzer".*

SYSTEM OVERVIEW

To perform testing the operator fills a cartridge with sample, seals the cartridge with its snap closure, and inserts the cartridge into the Analyzer. Insertion of a cartridge activates the Analyzer. The single-use cartridge contains calibrating solution, a sample handling system and all the sensors for a panel of tests. The Analyzer automatically controls all steps in the testing cycle including fluid movement within the cartridge, calibration, continuous quality monitoring, and thermal control (for tests where this is required). This degree of automation, along with the ability to test fresh whole blood, eliminates many sources of error as well as time-consuming and costly steps inherent in other methods.

During the testing cycle, operator and patient identification numbers can be entered. When the testing cycle is completed, results are displayed and the test record is stored.

The test record can be transmitted to the Central Data Station where it can be printed and/or transmitted to the Laboratory Information System or Hospital Information System. An optional portable printer enables the operator to print results at the point of care without entry into the Central Data Station.

INTENDED USE

The i-STAT handheld analyzer and Hewlett-Packard Blood Analysis Module are intended for use with i-STAT cartridges for the *in vitro* quantification of various analytes in human whole blood. The i-STAT System should be used by health care professionals trained and certified to use the system and should be used according to the facility's policies and procedures.

IMPLEMENTATION

An i-STAT representative will assist in the implementation of the system and training of resource personnel. There are no special site requirements for the i-STAT System. See the index to locate the specific procedures required to use each component of the system:

Handheld Analyzer

Install batteries and check date and time on the Status page. Use the Electronic Simulator to verify the performance of new or repaired Analyzers.

HP Blood Analysis Module

The Hewlett-Packard Blood Analysis Module is sold and serviced by Hewlett-Packard Company. Contact your HP representative for information about implementation requirements for the Blood Analysis Module.

Portable Printer

Install batteries, attach the printer to the IR Link or Printer Cradle and load paper.

Central Data Station

The Central Data Station computer and printer require a table top space of approximately 24 x 18 inches and two power outlets. handheld analyzers transmit results through IR Links to the Central Data Station via cable. An i-STAT representative will assist each facility to determine cabling needs. See the index to locate the procedure to connect the IR Link to the computer.

Connect the keyboard, monitor, printer and mouse (if applicable) to the computer according to the computer manual. The vents of the computer should not be blocked. The work area should be free from extreme heat, dust, direct sunlight, strong magnetic fields (such as a defibrillator), liquids and corrosive chemicals. Install printer paper and ink cartridge according to the printer manual.

The instructions for configuring the computer and printer are covered in the Central Data Station section of this manual.

Interfacing

The Central Data Station can be interfaced to Laboratory Information Systems (LIS) and/or Hospital Information Systems (HIS) to automate billing and patient recordkeeping. i-STAT will install an AME (Automated Manual Entry) interface tailored to the individual information transfer needs of each facility. Each AME interface is described in a customized AME User's Guide. The AME interface requires no corresponding software installation from the LIS or HIS vendor. A two way protocol conforming to ASTM standards for LIS interfaces is also available but requires prior development and installation of the interface by the LIS/HIS vendor.

WARRANTY

i-STAT Corporation warrants that representations made for products which it distributes reflect the manufacturers' representations to i-STAT Corporation.

i-STAT Corporation warrants the original purchaser its manufactured products (excluding disposable or consumable supplies) to be free from defects in materials or workmanship for one year from the original date of purchase subject to these terms and conditions: Returns will not be accepted without authorization from an i-STAT Representative, and products must show no evidence of improper handling or operation, including unauthorized repairs and/or damage caused by batteries.

At its option, i-STAT Corporation may repair or replace defective products covered by this warranty. **i-STAT Corporation expressly disclaims all other warranties, whether express, implied, or statutory, including the warranty of merchantability and fitness of use.** In no event will i-STAT Corporation be liable for consequential damages arising out of the use of its products.

i-STAT Corporation offers a "Comprehensive Service Plan" which includes extended warranty, software upgrades, and a replacement program for loss resulting from theft or damage on certain components. Ask your i-STAT Representative for details.

The Hewlett-Packard Blood Analysis Module is sold and serviced by Hewlett-Packard Company. Contact your HP representative about warranty information for the Blood Analysis Module.

Note: Warranty Cards for the optional printers should be completed and mailed to the designated address—not to i-STAT. Warranty information on the Central Data Station computer will be sent by the manufacturer under separate cover.

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SYSTEM COMPONENTS

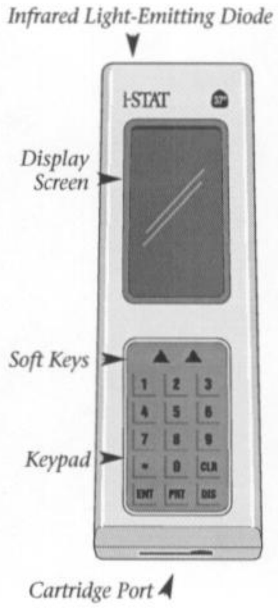
2

i-STAT
37°
1 2 3
4 5 6
7 8 9
* 0 CLR
ENT PRT DIS
i-STAT
EC8+

PATIENT CONNECTIONS ELECTRICALLY ISOLATED
ECG
SpO2/PLETH
ECG
SpO2
PLETH
BLOOD ANALYSIS
SETUP
CARTRIDGE LOCKED

HANDHELD ANALYZER

The i-STAT handheld analyzer is used in conjunction with i-STAT cartridges for the simultaneous quantitative determination of specific analytes in whole blood.



Specifications

Dimensions:	Width	6.41 cm (2.52″)
	Length	20.97 cm (8.26″)
	Depth	5.21 cm (2.05″)
Weight:	520 grams (18.34 oz)	
Power:	Two 9 volt lithium batteries (see specifics below)	
Calibration:	Factory (electronic, mechanical, thermal, pressure)	
Memory/Clock Back-up Power:	Lithium battery	
Display:	Dot matrix supertwist liquid crystal	
Communication Link:	Infrared light-emitting diode	
Operating Temperature:	16–30°C (61–86°F)	
Transport Temperature:	-10–50°C (14–122°F)	
Relative Humidity:	0–65% (minimum) noncondensing	
Barometric Pressure:	300–1000 mmHg	

Software

All analyzer functions are controlled by software that can be updated as additional tests and features are developed.

Power

The analyzer is powered by two 9 volt batteries. A minimum of 250 uses can be expected before replacement; overall uses for a set of new batteries is dependent on cartridge type *(cartridges that require thermal control consume power at a faster rate because of heating)*. The analyzer will indicate when battery replacement is needed with a message on the display screen. The battery compartment is accessed through a door on the underside of the analyzer.

A separate lithium battery internal to the analyzer maintains the clock/calendar and stored results. This battery should last for seven years.

The analyzer has no on/off switch. It is automatically activated when a cartridge is inserted. The analyzer automatically deactivates after 45 seconds of inactivity. Pressing the display key activates the display screen for viewing results and accessing the menu.

Cartridge Port

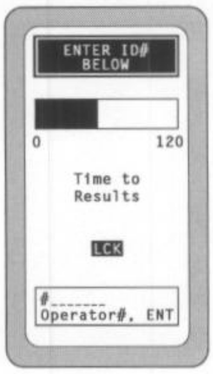
The cartridge containing a sample is inserted into the analyzer through the cartridge port. When properly inserted, the cartridge activates the analyzer.

Infrared Light-Emitting Diode

The infrared light-emitting diode (LED) transmits test records from the analyzer to a receiver on an IR Link, which can be connected to a portable printer and/or a Central Data Station computer.

Connector

When activated, the analyzer makes electrical contact with a cartridge or the Electronic Simulator by bringing an internal connector down upon the contact pads in the cartridge or Electronic Simulator. The connector locks the cartridge in the analyzer during the testing cycle as indicated by the LCK prompt on the display screen.



ENTER ID#
BELOW

Time to
Results

#_______
Operator#, ENT

Thermal Control and Barometric Pressure Sensor Subsystems

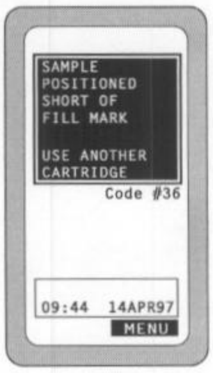
The handheld analyzer contains a thermal control subsystem with thermistors and heating contact wires. It controls the temperature of the zone in the cartridge which contains the silicon chips, sensors and fluids that come into contact with the sensors to 37ÞC. This function is activated automatically when a cartridge containing tests which require thermal control at 37ÞC is inserted into the analyzer.

The analyzer also contains a solid state barometric pressure sensor which determines ambient atmospheric pressure used for the PO_2 sensor calibration.

Test Cycle

The test cycle is initiated by the insertion of a cartridge into the analyzer. During the test cycle the following functions are performed by the analyzer:

- electrical contact is made with the cartridge
- cartridge type is identified
- calibration fluid is released to the sensors
- barometric pressure is measured *(when tests that require thermal control are present)*
- sensors are heated to 37ÞC *(when tests that require thermal control are present)*
- electrical signals generated at the sensors are measured
- calibrant solution is displaced with sample
- electrical signals generated at the sensors are measured
- operator and patient ID numbers are accepted
- blood gas and patient parameters are accepted
- results are calculated and displayed
- results are stored



SAMPLE
POSITIONED
SHORT OF
FILL MARK

USE ANOTHER
CARTRIDGE
Code #36

09:44 14APR97

If the analyzer detects the failure of a quality check during the testing cycle, the cycle is halted and a message identifying the condition and action to be taken is displayed.

Storage of Results

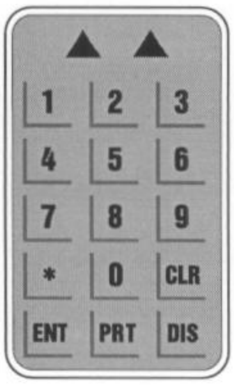
The results of all tests are stored automatically. The analyzer can store 50 test records. A test record consists of a set of results, the operator and patient identification number entered by the operator, blood gas parameters entered by the operator *(when applicable)*, the date and time the test was performed, the serial number of the analyzer, the number of times the analyzer has been used, and the software version that is installed in the analyzer. Quality check codes that may appear during the test cycle that indicate a detected problem with the sample, calibrant solution, sensors, mechanical or electrical functions of the analyzer are also stored. Stored test records are accessed through the Stored Results option on the Menu page described later in this section.

Display Screen

Test results, operator prompts, and other messages are displayed on the handheld analyzer screen.

Keypad

There are 15 labeled keys and two smaller unlabeled keys (soft keys) located directly below the display screen:

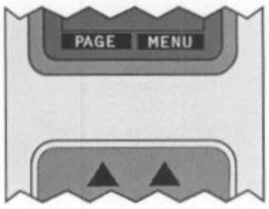


DIS	The display key is pressed to activate the display screen in order to recall the most recently displayed test results to the screen or to access the Menu page.
ENT	The ENT (enter) key is pressed in response to a prompt on the display screen to complete an action, such as entering an operator or a patient identification number.
CLR	The CLR (clear) key is pressed to erase an incorrect number when entering an identification number. Pressing the CLR key backs the cursor (flashing blank) one space and erases the number in that space.
Numbered	The "0" through "9" keys are used to enter operator and patient identification numbers, to change the time and date, and to make selections from menu options.
PRT	The PRT (print) key is pressed to send selected test records from the analyzer to the portable printer. The printer will automatically print out the test records when the PRT key is pressed.
*	The * key has several functions. It serves as a decimal when entering blood gas parameters; it is pressed to send a set of displayed results (test record) to the Central Data Station; exit a page and return to the results page when indicated by the prompts at the bottom of the screen; stop transmission of test records from the analyzer to the portable printer as indicated by the PRINTING...* (STOP) prompt.

Soft Keys

The two soft keys directly below the display screen are activated by the software when needed. When activated, the soft key's function or label will appear in an inverse video box (dark background, light letters) on the bottom of the screen, directly above the key.

SOFT KEY LABELS

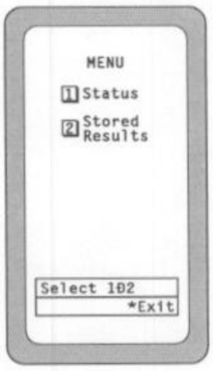


PAGE	This key is pressed to access additional display screens when certain analyzer functions require more space than a single screen allows. Examples: The page key will appear when viewing test records from certain cartridges that have numerous results and therefore require two pages, or when the operator needs access to an additional input screen for entering blood gas parameters such as the patient's temperature.
MENU	This key is pressed to view the Menu page. It is activated after a patient identification number is stored with a set of test results and after the beep when the display key is pressed.
CLKSET	This key is pressed to enter the clock-setting function. The CLKSET (clockset) key is activated when the Status page is displayed (see below).
←→	The arrow keys are activated when the clock-setting function is entered. Each time a key is pressed, the cursor moves forward (→) or backward (←) one position.
Page↑ Page↓	The page arrow keys are activated when option 1 or 2 is selected from the Stored Results page (see below). This allows the operator to page forward (↑) and backward (↓) through the 10 pages of stored test records.

Menu Page Options

The Menu page has two numbered options, Status and Stored Results.

MENU PAGE

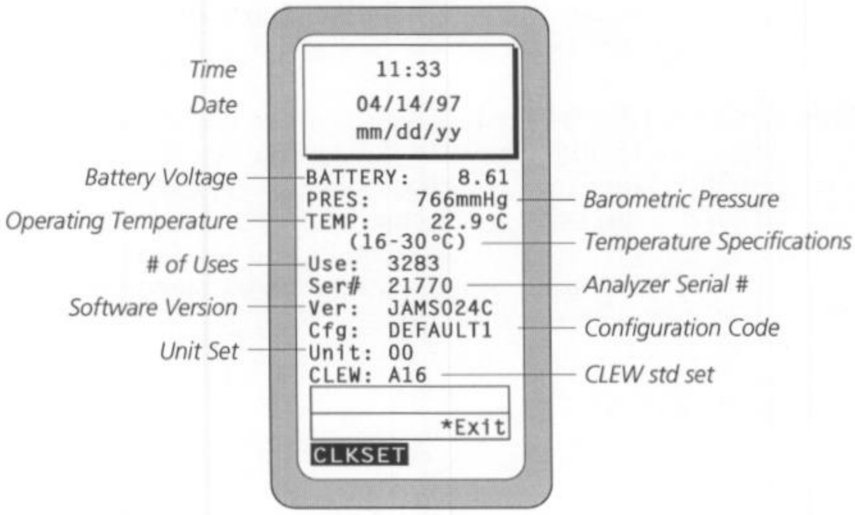


```
MENU
1 Status
2 Stored
  Results

Select 1Ð2
     *Exit
```

Status The "1" key is pressed to display the Status page which contains information about the condition or "status" of the analyzer.

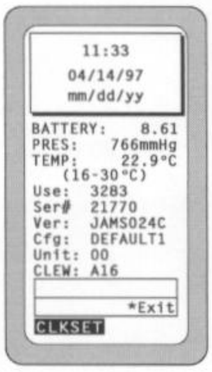
STATUS PAGE



```
11:33
04/14/97
mm/dd/yy
BATTERY:    8.61
PRES:    766mmHg
TEMP:     22.9°C
    (16-30°C)
Use:  3283
Ser#  21770
Ver:  JAMS024C
Cfg:  DEFAULT1
Unit: 00
CLEW: A16

           *Exit
CLKSET
```

If the date and time displayed on the status page is incorrect, it may be changed using the following procedure. Changing the time and date of the clock will not change the time and date stored with a set of results.



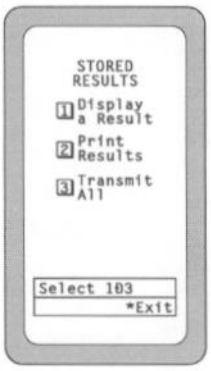
```
    11:33
  04/14/97
  mm/dd/yy
BATTERY:    8.61
PRES:    766mmHg
TEMP:     22.9°C
   (16-30°C)
Use:  3283
Ser#  21770
Ver:  JAMS024C
Cfg:  DEFAULT1
Unit: 00
CLEW: A16

           *Exit
CLKSET
```

1. Press the CLKSET soft key to enter the clock-setting function. The current time and date will appear and the cursor (-) will be flashing under the first digit of the hours. Both soft keys are activated as arrows to move the cursor.

   The clock is 24 hours, therefore AM or PM is not specified. The format for time is hours and minutes (hh:mm). The format for the date is month, day, and year (mm/dd/yy), as indicated on the display.

2. Press the arrow keys until the cursor is under the digit to be changed. To change the digit, press the correct numbered key. The new digit will appear and the cursor will move to the next position. If an invalid number is pressed, the cursor will not move to the next position; it will remain at that position until a valid number is pressed. When all the digit changes have been made, press the ENT key to set the clock. If an invalid number was not changed before the ENT key is pressed, the clock will revert to its original setting.



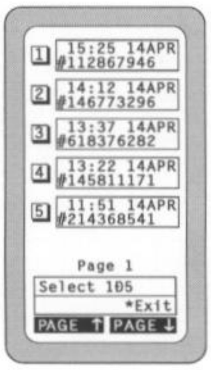
```
   STORED
   RESULTS
 1 Display
   a Result
 2 Print
   Results
 3 Transmit
   All

Select 103
           *Exit
```

Stored Results

Test records are listed by patient identification number and date and time of the test. Five test records are listed on each of 10 pages. The most recent test record is always stored in position one on page one. When the storage capacity is reached, the oldest test record (position five on page 10) is removed each time a new test record is added. If a storage position is empty or the test record is corrupted, the message INVALID or NO DATA will appear in the position.

Electronic Simulator tests are stored as PASS or FAIL with the failure code letter(s). If a test cycle is not completed, a code will appear indicating which quality check was not passed.

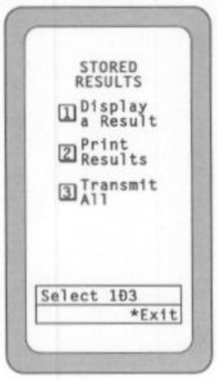


```
1  15:25 14APR
  #112867946
2  14:12 14APR
  #146773296
3  13:37 14APR
  #618376282
4  13:22 14APR
  #145811171
5  11:51 14APR
  #214368541

     Page 1
Select 105
           *Exit
PAGE ↑  PAGE ↓
```

Display a Result

The "1" key is pressed to access the test records for this option. The PAGE arrow soft keys are used to page forward (↑) or backward (↓). The test record to be displayed is selected by pressing the numbered key ("1" to "5") corresponding to the record's position. Electronic Simulator results and messages cannot be recalled to the screen.



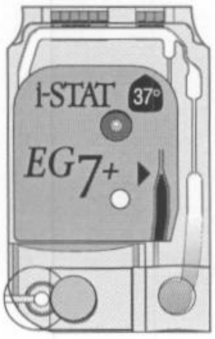
STORED
RESULTS
1 Display a Result
2 Print Results
3 Transmit All

Select 1–3
*Exit

Print a Result The "2" key is pressed to access the test records for this option. Any number of records can be selected for printing on the portable printer. The PAGE arrow soft keys are used to page forward (↑) or backward (↓). The records to be printed are selected by pressing the numbered keys ("1" to "5") corresponding to their positions. Printing is initiated by pressing the PRT key. Messages cannot be printed.

Transmit All The "3" key is pressed to transmit all stored test records, including those for the Electronic Simulator, to the Central Data Station via an IR Link. Transmission does not erase the test records from the analyzer's memory. The Central Data Station recognizes and ignores test records that have been transmitted before.

CARTRIDGE



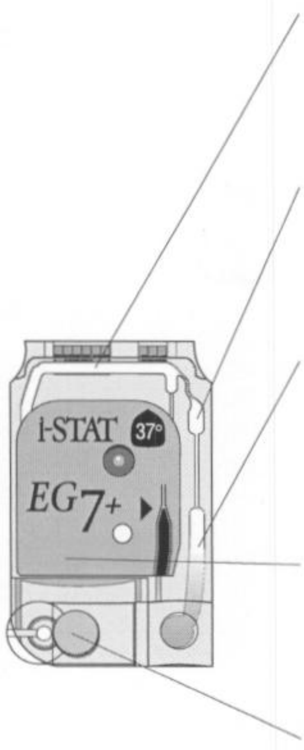
Each cartridge contains:

- A calibrant solution
- A sample handling system
- A waste chamber
- An array of miniaturized sensors
- Conductive pads to make electrical contact with the analyzer
- Heating elements *(when tests require thermal control at 37°C, a 37° symbol appears on the cartridge label, pouch and packaging)*

Calibrant Solution and Calibration

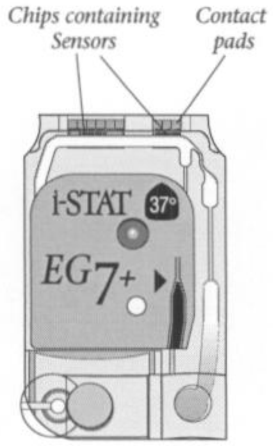
Cartridges are self-calibrating. Every cartridge includes a sealed foil pack which contains a calibrant solution with a known concentration of each analyte. During the first part of the testing cycle the calibrant solution is automatically forced out of the foil pack and over the sensors. The signals produced by the sensors in response to the calibrant solution are stored. Once this sequence is completed, the analyzer automatically moves the sample over the sensors. By comparing the sensors' responses to the sample with that of the calibrant, the concentration of each analyte in the sample is calculated. A message and quality check code will be displayed if calibration fails. Quality check codes and messages are described in the section of this manual that covers troubleshooting.

Sample Handling System



Sensor Channel	The sensor channel directs the sample from the sample chamber to the sensors. An extension of this channel becomes a waste chamber to receive the calibrant solution as it is displaced by the sample.
Air Chamber	The air chamber between the sample chamber and sensor channel creates an air segment between the calibrant solution and the sample to prevent the two from mixing. The air segment is monitored by the analyzer.
Sample Chamber	The sample chamber includes the sample well and the channel leading from the well up to the fill mark. When filled, the sample chamber contains sufficient sample for testing. Sample volume and placement are monitored by the analyzer.
Bladder	The bladder (concealed by the label) is connected to the sample well. The analyzer presses on the bladder to displace calibrant solution from the sensors and to move the sample from the sample chamber to the sensors.
Snap Closure	The closure is snapped over the sample well to create an airtight seal which is needed for fluid movement within the cartridge. The closure also ensures that calibrant and sample are contained within the cartridge during the testing cycle and subsequent disposal.
Air Vent	An air vent on the underside of the cartridge, beyond the fluid front, allows the calibrant and the sample to flow forward, but not out of the cartridge.
Waste Chamber	A waste chamber (beneath the cartridge label) is present to hold calibrant fluid after it has been used in testing.

Sensors



The sensors are electrodes microfabricated on silicon chips. Sensing functionality is imparted to the electrodes by coatings of chemically sensitive films such as ion-selective membranes and enzyme layers. Each sensor is connected to a contact pad by a signal line.

The sensors respond to the calibrant solution and/or the sample producing measurable signals that are related to concentration. The performance characteristics for each sensor are described in the Cartridge and Test Information section. The principles of the measurements are covered in the section on theory.

Contact Pads

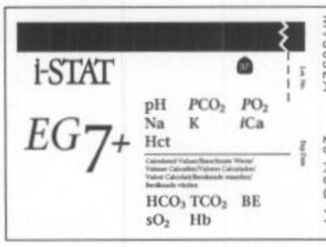
The contact pads conduct the signals generated at the sensors to the analyzer via the internal connector.

Heating Elements

Heating elements are present on cartridges that contain tests requiring thermal control at 37ÞC. Heating elements are located on the underside of the chips containing the micro-fabricated electrodes, and are heated by contact with heater wires in the analyzer.

Packaging

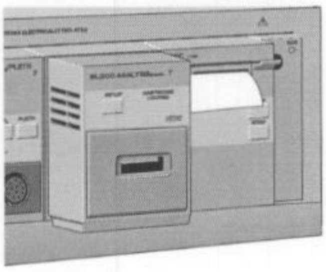
Each cartridge is sealed in a pouch for protection during storage. Labeling on the carton, box and pouch identify the panel name, list of the tests included in the panel, the lot number and the expiration date of the cartridge. The cartridge is labeled with the panel name and thermal control symbol *(where required)* only. If the pouch has been punctured, the cartridge should not be used.



Storage Conditions

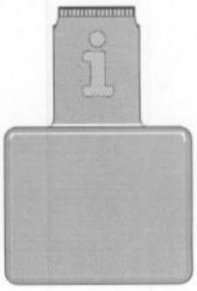
The main supply of cartridges should be stored at 2–8ÞC (35–46ÞF). Cartridges must be brought to room temperature before removing from pouches and use. See the Cartridge and Test Information section of this manual for the required time to bring cartridges to room temperature. Cartridges in use may be stored at room temperature (18–30ÞC or 64–86ÞF) for two weeks. The calendar on the cartridge box should be used to indicate the two week room temperature expiration date.

HP BLOOD ANALYSIS MODULE



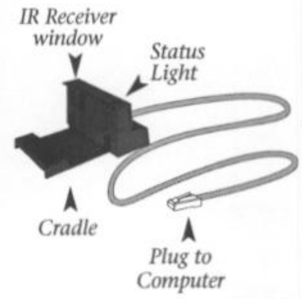
The Hewlett-Packard Blood Analysis module is a component for HP patient monitors. Caregivers can perform blood analysis in real time right at the bedside using i-STAT cartridges, and see testing results along with other physiological parameters on the patient monitor's screen. The Blood Analysis Module essentially performs the same basic functions as an i-STAT handheld analyzer, although several features of the user interface have been optimized or appropriately adapted for a patient monitoring environment. Only those operating instructions and other information that apply to both the i-STAT handheld analyzer and HP Blood Analysis Module are covered in this System Manual. For specifications, monitor operating instructions and other information relating specifically to the Blood Analysis Module, refer to the appropriate Hewlett-Packard user documentation or contact your HP representative or service center.

ELECTRONIC SIMULATOR



The Electronic Simulator (both external and internal) is a quality control device for the analyzer. It simulates two levels of electrical signals which stress the analyzer's signal detection function both below and above measurement ranges. While the analyzer performs internal electronic checks and calibration during each testing cycle, the Electronic Simulator test provides an independent check on the ability of the analyzer to take accurate and sensitive measurements of voltage, current and resistance from the cartridge. An analyzer will pass or fail this electronic test depending on whether or not it measures these signals within limits specified in the analyzer software. Because the Electronic Simulator test will fail if high relative humidity interferes with the measurements, it is not necessary to record humidity reading wherever the analyzers are in use. Use of the Electronic Simulator is described further in the section on quality control.

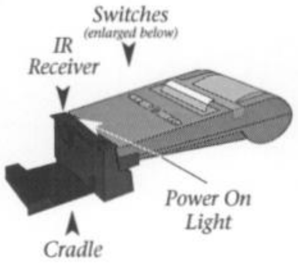
IR LINK



The IR receiver in the IR Link converts the infrared signals from the handheld analyzer to electrical signals which are transmitted to the Central Data Station via a cable. The cradle ensures proper alignment during transmission. The status light indicates when the computer is ready to receive a transmission (green), not ready (red), and when transmission is in progress (blinking). The receiver indicates with a beep whether the transmission has been successful (single high pitched beep) or not successful (three low pitched beeps).

PORTABLE PRINTER

i-STAT supplies a modified Hewlett-Packard HP 82240B Infrared Printer for use with the handheld analyzer. This battery powered printer can be used independently of the Central Data Station to obtain a printout of a test record at the point of care. The printer is attached to an IR Link or an i-STAT Printer Cradle (without receiver) to ensure proper alignment between the analyzer and printer.



The printer is powered by four 1.5 volt alkaline AA batteries. Battery life for alkaline batteries is approximately 450 test records. After about 10 minutes of inactivity, the printer (without the optional AC adapter) will switch to low power mode to conserve batteries. To reactivate the printer, press the paper advance button.

To prolong battery life, set print contrast to the lightest comfortable setting, turn the printer off when it is not in use, and use the optional AC adapter when possible. Note: Because the printer may required supplemental batter power during heavy printing, batteries should be installed when the AC adapter is being used.

CENTRAL DATA STATION

i-STAT supplies a desktop computer with eight ports for any combination of IR Links, Hewlett-Packard Patient Data Servers, or additional Central Data Stations. The i-STAT Central Data Station software allows simultaneous collection of displayed or stored test records from all analyzers in the facility. Test records can be edited and trended on the Central Data Station, can be printed on a printer attached to the computer, and can be transmitted to a Laboratory Information System, Hospital Information System or another Central Data Station. Transmission to a LIS or HIS requires prior installation of an AME or ASTM interface.

The computer is shipped with its complete set of manuals. All instructions needed to use the computer as part of the i-STAT System are in a separate section of this System Manual.

PRINTER

i-STAT offers a printer as an option for use with the computer. The printer can be used to print individual test records or a trend report. The printer is shipped with its complete set of manuals.

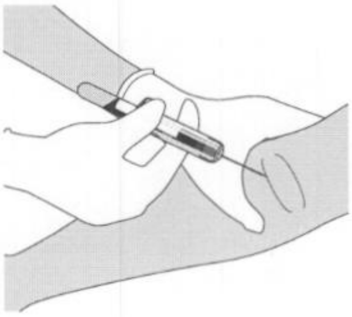
SAMPLE COLLECTION 3

SPECIMEN COLLECTION

The specimen used to fill a cartridge must be collected and handled properly to ensure that the results represent the patient's current status. Only fresh whole blood samples either without anticoagulant or with an appropriate heparin anticoagulant are recommended for use with the i-STAT System. Specimens should be collected according to the facility's policies and procedures. The following precautions (taken from references 1-6 at the conclusion of this section) can help avoid potential sources of error prior to filling a cartridge (pre-analytical error).

Venipuncture

Venipunctures are typically performed for acid-base balance, electrolyte, metabolic and hematologic studies. Observe the following precautions:



- Avoid drawing from an arm with an I.V. line. I.V. solutions will dilute the sample and may interfere with the tests.
- Avoid localized stasis which can increase potassium and pH results and decrease ionized calcium results. If a tourniquet is applied for more than one minute while looking for a vein, release and reapply after two to three minutes.
- Allow the tourniquet to remain in place until all blood is withdrawn to prevent changes in ionized calcium and pH results.
- Avoid extra muscle activity, such as clenching and unclenching the fist, which may increase potassium results.
- Avoid hemolysis (bursting of red cells) by allowing residual alcohol to dry over the puncture site. Hemolysis will cause an increase in potassium results and a decrease in calcium results.
- If the cartridge cannot be filled immediately, collect a sample into an evacuated blood collection tube or a syringe containing heparin (sodium, lithium or balanced) anticoagulant. For ionized calcium measurements, balanced heparin or <10 IU/mL of sodium or lithium heparin is recommended. Balanced heparin or low volume heparin is used in some commercially available blood gas syringes. Becton-Dickenson's lithium heparin evacuated tubes contain approximately 15 IU/mL when filled to capacity.
- Fill evacuated tubes and syringes with anticoagulant to capacity. Incomplete filling will cause higher heparin to blood ratios which will decrease ionized calcium results and may affect other results.

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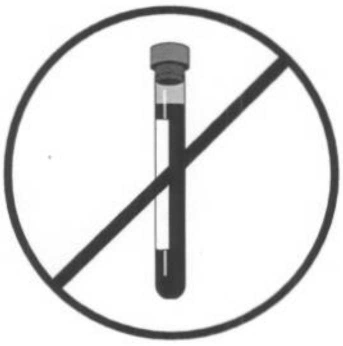
- Gently mix blood and anticoagulant immediately to avoid clotting: invert an evacuated tube 5 to 10 times and roll a syringe between the palms for at least five seconds in two directions.
- Collect vacuum tubes in the prescribed sequence to avoid interference due to carry over of anticoagulant from one tube to the next: red, blue, green, lavender, grey. If a blue stoppered tube is drawn, draw a 5mL red stoppered discard tube before drawing the green stoppered tube.
- Do not expose the sample to air when testing for ionized calcium, pH, PCO_2 or PO_2
- For the most accurate results, test samples immediately after draw. If testing is delayed, remix evacuated tubes by gentle inversion and syringes by rolling between the palms for 5 seconds, and then discard the first drop of blood. Test samples within 10 minutes after draw.

Arterial Puncture

Arterial punctures are performed to access gas exchange status. pH, PCO_2 and PO_2 values change with changes in ventilatory support at a rate dependent on underlying conditions. Samples should be drawn after these changes have stabilized.

- Evacuated tubes are not recommended for blood gas analysis.
- Follow the directions carefully when using pre-prepared blood gas kits and syringes. Fill syringes to the recommended capacity or use the least amount of liquid heparin anticoagulant that will prevent clotting. Underfilling syringes which contain liquid heparin will decrease results due to dilution and will decrease ionized calcium results due to binding.
- For ionized calcium testing, use balanced or low volume heparin blood gas syringes.
- Mix blood and anticoagulant by rolling between the palms for at least 5 seconds. Then invert the syringe repeatedly for at least 5 seconds.

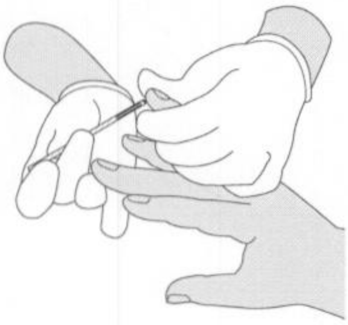


- Avoid or remove immediately any air drawn into the syringe and maintain anaerobic conditions.
- For the most accurate results, test samples immediately after draw. If testing is delayed, remix and discard the first drop of blood. Test samples within 10 minutes.
- Fill the cartridge before icing the sample for transportation. Icing will increase potassium and will affect oxygen levels in samples collected in plastic syringes.

In-Dwelling Line

- Back flush line with a sufficient amount of blood to remove intravenous solutions, heparin or medications that may contaminate the sample. Three to six times the volume of the catheter, connectors and needle is recommended.

Skin Puncture



- Avoid hemolysis (bursting of red cells) due to vigorous massaging or "milking". Hemolysis will cause an increase in potassium results and a decrease in calcium results. To increase blood flow, massage a finger gently from about three inches from the tip to the fleshy portion of the tip.
- Avoid hemolysis by allowing residual alcohol to dry over the puncture site.
- Wipe away the first drop of blood as it may contain excess tissue fluid which can increase potassium results and dilute other test results.
- Avoid drawing air into the capillary tube.
- Most heparinized capillary tubes are not suitable for ionized calcium measurements due to the high concentration of heparin (approximately 50 IU/mL). Use balanced heparin tubes or plain tubes.
- Test samples collected in capillary tubes immediately to avoid clotting (especially in neonates whose blood may clot more quickly) .
- Follow the facility's policy and procedure for warming (arterializing) an infant's heel.

SAMPLE TRANSFER DEVICES

Dispensers

To avoid the use of needles when transferring a blood sample from an evacuated tube, a dispenser can be used. Do not use dispensers that would introduce air into the sample when ionized calcium, pH or PCO_2 are being measured.

Capillary Tube

While a sample can be transferred directly from a skin puncture to a cartridge, a capillary tube is preferred.

Syringe

A 1cc syringe (such as a tuberculin) and needle (no smaller than 20 gauge) can be used to withdraw a sample from an evacuated tube. Take care not to draw air with the sample when ionized calcium, pH or PCO_2 are being measured.

REFERENCES

1. National Committee for Clinical Laboratory Standards, Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture, 3rd ed.; Approved Standard, NCCLS publication H3-A3 (Villanova, PA: NCCLS, 1991).

2. National Committee for Clinical Laboratory Standards, Procedures for the Collection of Diagnostic Blood Specimens by Skin Puncture, 3rd ed.; Approved Standard, NCCLS publication H4-A3 (Villanova, PA: NCCLS, 1991).

3. National Committee for Clinical Laboratory Standards, Considerations in the Simultaneous Measurement of Blood Gases, Electrolytes, in Whole Blood; Proposed Guideline, NCCLS publication C32-P (Villanova, PA: NCCLS, 1993).

4. National Committee for Clinical Laboratory Standards, Ionized Calcium determinations: Precollection Variables, Specimen Choice, collection, Handling; Proposed Guideline, NCCLS publication C31-P (Villanova, PA: NCCLS, 1993).

5. National Committee for Clinical Laboratory Standards, Percutaneous Collection of Arterial Blood for Laboratory Analysis, 2nd ed.; Approved Standard, NCCLS publication H11-A (Villanova, PA: NCCLS, 1992).

6. National Committee for Clinical Laboratory Standards, Blood Gas Pre-Analytical Considerations: Specimen Collection, Calibration, and Controls; Approved Guideline, NCCLS publication C27-A (Villanova, PA: NCCLS, 1993).

OPERATING PROCEDURES 4

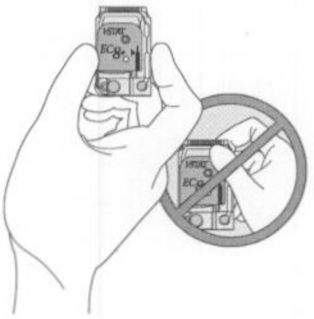
i-STAT HANDHELD ANALYZER, HP BLOOD ANALYSIS MODULE AND CARTRIDGE

Select the Cartridge

While the cartridge is not fragile it should be handled as follows to avoid difficulty in filling or rejection by the Analyzer.

NOTE:

Fill, seal and insert cartridge without interruption or delay



- Do not remove a cartridge from its protective pouch until the pouch is at the temperature of the room where it is to be used; condensation on the cartridge pads may prevent proper contact with the Analyzer. See Cartridge and Test Information sheets for time required for cartridges to come to room temperature. Use the cartridge immediately after removing it from its protective pouch.

- Do not contaminate the contact pads with finger prints or talc from gloves as the Analyzer may not be able to make proper contact with the cartridge.

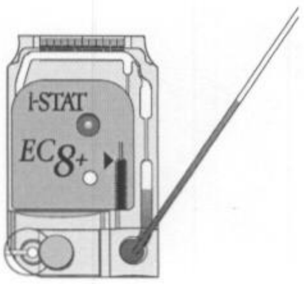
- Do not exert excessive pressure over the central area of the label as the calibrant pack underneath could burst prematurely.

- Do not block the air vent as the sample will not be able to flow to the fill mark and the calibrant solution will not be able to flow to the sensors.

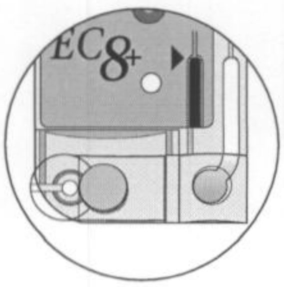
- Do not use a cartridge on which blood or any other fluid is spilled, as the Analyzer's connector may be contaminated.

Fill the Sample Chamber

Place the cartridge on a flat surface or hold it in a horizontal position. Do not hold cartridge between the fingers if using a syringe with needle to fill. Direct the tip of the syringe, capillary tube or dispenser into the sample well. Dispense sample slowly and steadily until it reaches the fill mark indicated on the cartridge label. *(Leave some sample in the sample well)*



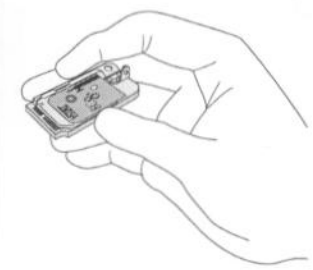
The cartridge is designed to fill correctly. The conditions described below are likely to occur only during the training period.



- If the sample goes slightly beyond the fill mark, the cartridge can still be used. If the cartridge is overfilled, the Analyzer will detect this condition and display SAMPLE POSITIONED BEYOND FILL MARK.

- If air bubbles are trapped in the sample chamber, discard the cartridge and fill another. This condition would be detected as INSUFFICIENT SAMPLE.

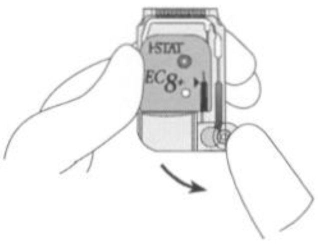
- If the sample reaches the fill mark, but the sample well is left completely empty, an INSUFFICIENT SAMPLE condition may be detected.



- If the sample well fills but the rest of the sample chamber does not, ensure that the air vent is not blocked. Tilt the cartridge slightly so that gravity aids the flow. When the sample starts to flow into the chamber, return the cartridge to the horizontal position. If the sample is considerably short of fill mark, the Analyzer will detect the condition and display SAMPLE POSITIONED SHORT OF FILL MARK.

- If the sample well is so full that sample is seen above the sample well after the sample chamber is filled, do not wipe or absorb the excess with a gauze or tissue but draw the excess back into the syringe or a capillary tube.

- If the sample spreads over the outside of the sample well, an airtight seal may not form upon closure of the cartridge. The message UNABLE TO POSITION SAMPLE will be displayed and another cartridge will have to be used.



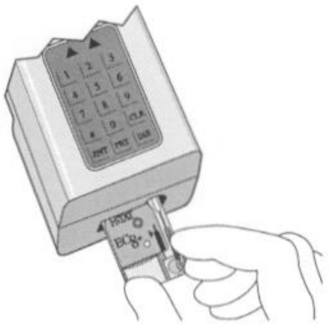
Seal the Cartridge

Fold the snap closure over the sample well. Press the rounded end of the closure until it snaps into place.

- Avoid exerting excessive pressure on the closure directly over the sample well as doing so may push the sample beyond the fill mark. The Analyzer will detect this condition and display SAMPLE POSITIONED BEYOND FILL MARK.

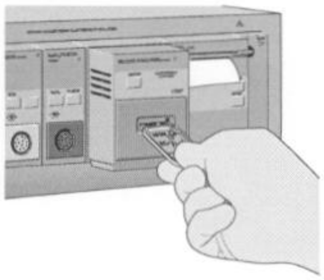
- Closing the cartridge before the sample chamber has filled will stop the flow of the sample. The Analyzer will detect this condition and display SAMPLE POSITIONED SHORT OF FILL MARK.

- Failure to close the cartridge before inserting it into the Analyzer will prevent sample movement and can cause the sample to flow backward and out of the sample well. The Analyzer will detect this condition and display UNABLE TO POSITION SAMPLE.



Insert Cartridge Into Analyzer

Orienting the cartridge with the contact pads facing up and toward the cartridge port, push the cartridge slowly and smoothly through the cartridge port until it will go no further. When the cartridge is fully inserted, the sample well area will remain outside the port. The Analyzer will acknowledge proper insertion by displaying the CONTACTING CARTRIDGE message. The display will change to TIME TO RESULTS with the time bar counting down.



The LCK prompt is displayed indicating that the cartridge should not be removed.

Caution: *Do not attempt to remove a cartridge during the testing cycle. The force that would be necessary to do so could damage the Analyzer.*

Note: Several features of the HP Blood Analysis Module's user interface have been optimized or appropriately adapted for a patient monitoring environment. Therefore, many of the specific procedures discussed in the following section may vary slightly from what is required when using the handheld analyzer. Refer to the appropriate Hewlett-Packard user documentation for these procedures.

Enter Identification Numbers

A prompt indicating that operator and patient identification numbers need to be input appears on the display screen during the test cycle and remains visible until the identification numbers have been entered.

Operator The operator prompt will appear in a box at the bottom of the screen with the first of seven blanks flashing. Enter an operator identification number of up to seven digits by pressing the numbered keys. If an incorrect digit is added, it can be erased by pressing the CLR key. After the identification number is completed, press the ENT key to signal the analyzer that the last digit has been entered.

```
#_______
Operator#, ENT
```

After the ENT key is pressed, the prompt "Repeat #, ENT" appears in the box, and the entered operator identification number is replaced by seven blanks, the first of which is flashing. Repeat the operator identification number by pressing the numbered keys and press the ENT key to signal the analyzer that the last digit has been entered.

```
#_______
Repeat#,  ENT
```

When the ENT key is pressed, the analyzer compares the two entered operator identification numbers. If the entered numbers are not identical, the message "ID DID NOT MATCH START AGAIN" appears in the center of the screen. The box reverts back to its starting state with the operator prompt. The operator identification number entry must be repeated. If the entered numbers are identical, the operator identification number is accepted and stored with the results.

NOTE:

If the analyzer display deactivates before all parameters are input, press the display key, then press the PAGE key twice to re-access the data entry screen.

Enter Identification Numbers

Patient After the operator identification number is stored, the patient identification number prompt will appear in the box with the first of twelve blanks flashing. Enter a patient identification number of up to twelve digits using the same procedure described for inputting the operator identification number.

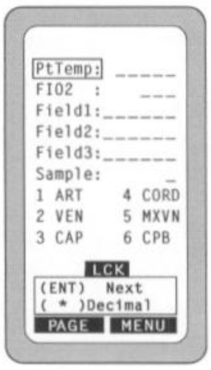
```
#____________
Patient#,  ENT
```

```
#____________
Repeat#,  ENT
```

Operating rooms and "codes" present a unique testing situation in that tests are run repeatedly on the same patient. Pressing the DIS key when prompted for Patient ID will recall the last Patient ID entered into the analyzer. The repeat request for Patient ID may also be entered by pressing the Display key.

Enter Blood Gas and Patient Information

After the patient identification number is entered, the PAGE key is activated allowing access to an additional data entry screen. (If results are already displayed, press the PAGE key twice to access the data entry screen). The cursor will be flashing at the first input area. Use the numbered keys to input information and press the ENT key to advance to the next input area (or to return to the first area from the last input area). Invalid numbers will be ignored, and and incorrect inputs can be corrected using the CLR key as a backspace.



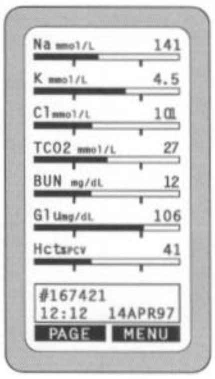
```
PtTemp: -----
FIO2  :   ---
Field1:------
Field2:------
Field3:------
Sample:     _
1 ART   4 CORD
2 VEN   5 MXVN
3 CAP   6 CPB
     LCK
(ENT)  Next
( * )Decimal
PAGE   MENU
```

NOTE:

Input of PT temperature and FIO_2 is only possible when a cartridge contains pH, PCO_2, and PO_2 sensors.

Pt Temp	Enter the patient's temperature in degrees Fahrenheit or Centigrade. Use the * key to enter a decimal point. The analyzer will interpret numbers between 50.0 and 110.0 as degrees Fahrenheit and between 10.0 and 45.0 as degrees Centigrade.
FiO_2	Enter an FIO2 value from 0 to 100, representing the number of liters or a percentage of the oxygen the patient is receiving. Use the * key to enter a decimal point.
Fields 1, 2 & 3	These are user-defined fields up to 6 digits (including a decimal point. These fields can be used to enter other blood gas parameters such as PEEP.
Sample	Enter the number corresponding to the sample type: 1 ART *(arterial)* 2 VEN *(venous)* 3 CAP *(capillary)* 4 CORD 5 MXVN *(mixed venous)* 6 CPB *(cardiopulmonary bypass)* When 6 (CPB) is chosen as the sample type, a special algorithm for hematocrit values is used. The algorithm infers a total protein level, assuming the pump priming solution dilutes the hematocrit and total protein equally. An adjusted hematocrit value is reported as Hct, CPB on both the analyzer display and printout. For more information about i-STAT hematocrit determinations during cardiopulmonary bypass procedures, see Technical Bulletin "Hematocrit Determinations Using the i-STAT System During Cardiopulmonary Bypass Procedures".

After data entry is complete, press the SAVE softkey. The softkeys will switch to YES and NO keys. If the data entry is correct, press the YES key and the data will be stored with the results. Press NO to return to the input screen to make corrections.



```
Na mmol/L      141
K mmol/L       4.5
Cl mmol/L      101
TCO2 mmol/L     27
BUN mg/dL       12
Glu mg/dL      106
Hct %PCV        41
#167421
12:12   14APR97
PAGE   MENU
```

View Results

The handheld analyzer will display test results once the cartridge has been unlocked and the LCK prompt disappears. Results will be displayed for 45 seconds. Results can be recalled to the display screen by pressing the display key.

Record Results

Results should either be transcribed onto a report form or transmitted to the portable printer or the Central Data Station. Care should be taken in transcribing results; most mistakes in patient testing occur during this step.

Remove the Cartridge

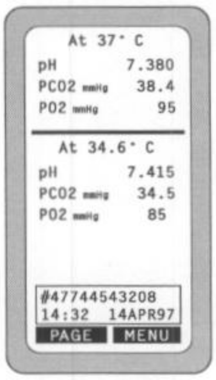
Remove the cartridge at any time after the LCK prompt disappears. Grasp the cartridge by the sides of the sample well and pull straight out. Discard the used cartridge in a container designated for biohazardous or contaminated material. Once a cartridge is removed, even if results are still displayed, the analyzer is ready to accept another cartridge.

DESCRIPTION OF DISPLAYED RESULTS

Results Display

Test results are displayed showing numerical concentration values. Bar graphs which depict the values in relation to reference ranges are also displayed. Blood gas results are not displayed with reference ranges. The reference range is marked on the bar by tick marks. When all test values are within their reference ranges, the tick marks will be centrally aligned. The bar graphs can be used as a visual cue for distinguishing between "normal" and "abnormal" results.

In example A, a patient's blood gas results are shown.



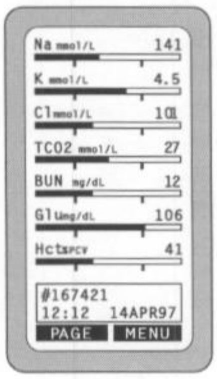
```
At 37° C
pH            7.380
PCO2 mmHg      38.4
PO2 mmHg         95

At 34.6° C
pH            7.415
PCO2 mmHg      34.5
PO2 mmHg         85

#47744543208
14:32  14APR97
```

Example A

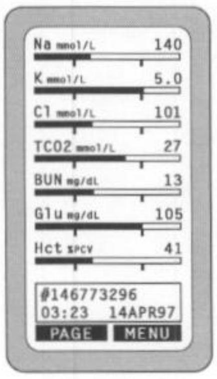
In example B, the patient results shown are normal. The potassium value is 4.5 mmol/L. The reference range programmed into the analyzer is 3.5 to 4.9 mmol/L.



```
Na mmol/L       141
K mmol/L        4.5
Cl mmol/L       101
TCO2 mmol/L      27
BUN mg/dL        12
Glu mg/dL       106
Hct %PCV         41
#167421
12:12  14APR97
```

Example B

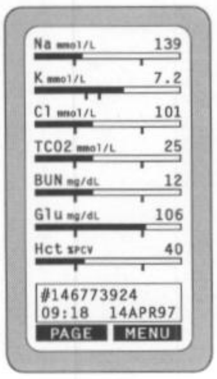
In example C, the potassium value is 5.0 mmol/L which is above the reference range but within the range of the bar.



```
Na mmol/L       140
K mmol/L        5.0
Cl mmol/L       101
TCO2 mmol/L      27
BUN mg/dL        13
Glu mg/dL       105
Hct %PCV         41
#146773296
03:23  14APR97
```

Example C

In example D, the patient's potassium value is 7.2. If the patient's test value exceeds the range of the bar in either direction, the bar is rescaled to show the test value relative to the reportable range. The reference range tick marks are then marked according to where they fall within the reportable range. In the example, the reference range is the same, but the bar now displays the entire reportable range of 2 to 9, and the potassium reference range is no longer centrally aligned on the bar.



```
Na mmol/L       139
K mmol/L        7.2
Cl mmol/L       101
TCO2 mmol/L      25
BUN mg/dL        12
Glu mg/dL       106
Hct %PCV         40
#146773924
09:18  14APR97
```

Example D

Reference Ranges

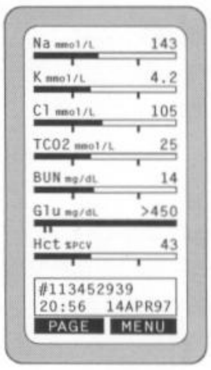
For tests where appropriate, reference ranges (sometimes referred to as normal ranges) are programmed into the analyzer and cannot be changed by the operator. The reference ranges are derived from the literature and are listed in the Cartridge and Test Information section. Variables such as sex, age, heritage and other demographic factors of a population may cause a shift in these ranges. Therefore, it is usually recommended that each facility determine its own reference ranges.

Reportable Ranges

The reportable range (sometimes referred to as the linear range), is the concentration range over which test results are valid. When a test result falls outside the reportable range it is flagged. Reportable ranges programmed into the analyzer can be found in the Cartridge and Test Information section.

Flags

When the analyzer detects an out-of-range result or an uncharacteristic sensor signal, the condition is indicated by a flag.

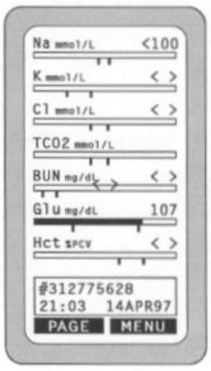


```
Na mmol/L       143
K mmol/L        4.2
Cl mmol/L       105
TCO2 mmol/L      25
BUN mg/dL        14
Glu mg/dL      >450
Hct %PCV         43
#113452939
20:56   14APR97
PAGE      MENU
```

Example E

> The ">" (greater than sign) indicates that a result falls above the displayed concentration value which represents the high end of the reportable range of the test. For example, if glucose results are displayed in mg/dL and a result is displayed as >450, as in example E, the result should be recorded as "greater than 450 mg/dL."

< The "<" (less than sign) indicates that the result falls below the displayed concentration value which represents the low end of the reportable range of the test. For example, if a glucose result is displayed as <20, the result should be recorded as "less than 20 mg/dL."



```
Na mmol/L      <100
K mmol/L        < >
Cl mmol/L       < >
TCO2 mmol/L
BUN mg/dL       < >
Glu mg/dL       107
Hct %PCV        < >
#312775628
21:03   14APR97
PAGE      MENU
```

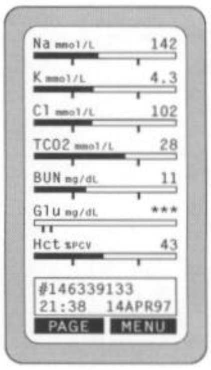
Example F

< > The "< >" flag indicates that the calculations for the test are dependent upon another test which has been flagged either "<" or ">." In example F, the sodium is <100. Because the calculations for potassium, chloride, BUN/Urea and hematocrit depend upon the sodium value, these tests are flagged "< >."

The "< >" flag will also be displayed for TCO_2, pH, PCO_2, HCO_3, anion gap, base excess, and sO_2 if the TCO_2 result is outside the reportable range. Because the values outside the reportable range of TCO_2 are essentially non-physiological, the TCO_2 range check is used as an additional quality check on the validity of the underlying pH and PCO_2 results.

When these flags occur, the sample must be tested by another type of analyzer in order to obtain results.

The < and > flags are not applied if a hematocrit sensor is present and the result is less than 7% PCV. This allows the use of aqueous calibration verification solutions with concentrations below or above the reportable ranges claimed and programmed into the analyzer software.



```
Na mmol/L       142
K mmol/L        4.3
Cl mmol/L       102
TCO2 mmol/L      28
BUN mg/dL        11
Glu mg/dL       ***
Hct %PCV         43
#146339133
21:38   14APR97
PAGE      MENU
```

Example G

*** Stars will appear in place of a concentration if the signals from that particular sensor are uncharacteristic (Example G). Uncharacteristic signals can be caused by a compromised sensor or by an interferent in the sample. Stars will also appear for any tests that depend on another test which is itself flagged with stars. The sample should be retested using another cartridge. If the stars reappear, refer to the section in this manual that discusses troubleshooting.

PORTABLE PRINTER

Turn Printer On

Place the handheld analyzer in the IR cradle. If the printer indicator light is not lit, turn the printer on by switching the on/off switch to the on (|) position. If the indicator light is not lit but the on/off switch is in the on position, reactivate the printer by pressing the paper advance switch.

Print Displayed Results

A displayed test record can be printed by pressing the PRT key.

The most recent test record can be printed only if a patient identification number has been entered or actively bypassed.

To recall a stored test record to the display screen, press the MENU soft key and select *Stored Results* by pressing the "2" key. From the *Stored Results* menu, select *Display a Result* by pressing the "1" key. Select the record to be displayed by pressing the key ("1" to "5") on the page (1 to 10) corresponding to the test record.

NOTE:

The message "PRINTING..." will be displayed in a reverse video box on the analyzer's display. Do not move the analyzer while the printing message is displayed as the printed results may be garbled.

Print Stored Results

Any number of test records can be printed without recalling the results to the screen. Press the MENU soft key and select Stored Results by pressing the "2" key. From the Stored Results menu, select Print Results by pressing the "2" key. Use the soft keys to page up or down through the 10 pages of stored test records. Press the "1" to "5" keys to select the desired records on each page. When a key is pressed, the number selected will reverse video (dark background, light lettering). To deselect a record, re-press the key—the number will return to light background, dark number. When all the test records desired are selected, press the PRT key. The message "PRINTING..." will be displayed while the records are transmitted to the printer. A record will take from 40 to 70 seconds depending on the number of tests in the record.

Abort Printing

To stop printing before all test records are printed, press the * key.

No Printout Allowed

A test record cannot be printed from a position displaying INVALID OR NO DATA, an Electronic Simulator test or a quality check message.

INFORMATION PRINTED

```
i-STAT System
Pt: 973621150
Pt Name:____________
Na________141
mmol/L
K_________4.4
mmol/L
TCO2_______41
mmol/L
iCa______1.24
mmol/L
Hct_______39%
Hb*________13 g/dL
       *via Hct
At 37C
pH______7.380
PCO2_____38.4 mmHg
PO2________95 mmHg
HCO3_______40
mmol/L
BE_________17
mmol/L
sO2*_______95 %
    *calculated
At Patient Temp
pH______7.415
PCO2_____34.5 mmHg
PO2________85 mmHg

Patient Temp  34.6C
FIO2________: 70
Sample Type __: ART
Field1______: 45.8
```

CENTRAL DATA STATION

Transmitting Results to the Central Data Station from a Handheld Analyzer

Place the handheld analyzer in the IR cradle. Check that the status light is green. Press the "*" key to transmit displayed results or use the *Transmit All* option from the *Stored Results* menu. Do not move the analyzer for the few seconds that the message TRANSMITTING is displayed on the handheld analyzer display screen.

Verification of Transmission from a Handheld Analyzer

During transmission, the IR status light will blink red and green will emit a fast clicking sound and the status light will continue to blink. The receiver will emit a slow click and while the computer verifies the integrity of the transmission.

Upon successful transmission of results, the IR receiver will emit a single high pitched beep. If the transmission is not successful, the IR receiver will emit three low pitched beeps. Should this occur, refer to the section in this manual that addresses the Central Data Station.

Information Transmitted from a Handheld Analyzer

The date and time the test was performed, operator and patient numbers entered by the operator, blood gas parameters entered by the operator, results, serial number of the handheld analyzer and its uses count, the software version in the handheld analyzer, and the PRC code are transmitted from the handheld analyzer to the Central Data Station.

Transmitting Results to the Central Data Station from a Hewlett-Packard Blood Analysis Module

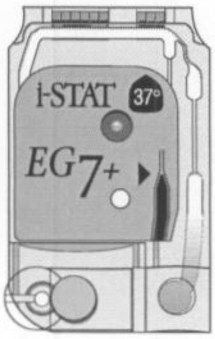
Test results from a Blood Analysis Module can be transmitted to the Central Data Station. An HP Patient Data Server running the HP Blood Analysis Interface is required. Refer to HP user and technical documentation for more information.

QUALITY CONTROL

5

Quality Control, as a component of an overall Quality Assurance program, consists of tests and procedures for monitoring and evaluating the analytical performance of a measurement system to assure the reliability of patient test results. As new technologies evolve, quality control regimens must match the requirements of the particular analytical system. i-STAT Corporation recognizes the importance of effective quality control for its analytical medical devices, and has developed a program that is tailored to the unique characteristics of the i-STAT System.

OVERVIEW



The i-STAT System performs blood analysis when a unit-use cartridge filled with a patient's sample is inserted into a handheld analyzer or Blood Analysis Module (as part of a Hewlett Packard Patient Monitoring System). The measurement methodologies are electrochemical, using microfabricated sensors housed in each cartridge to measure analyte concentrations directly in a single whole blood sample (i.e. no dilution nor reagent mixing steps are required).

Two characteristics of the i-STAT System which distinguish it from traditional laboratory equipment have significant impact upon the design of the quality control regimen: its intended use and the unit-use cartridge technology.

As the system is intended to be used by individuals not trained in laboratory science, the onus is upon the system's design to ensure that the quality of results is not dependent upon either user technique, skilled maintenance and calibration procedures, or the accompanying quality control regimens which ensure these procedures have been properly performed.

The use of unit-use cartridges frees the i-STAT system from these skilled maintenance and calibration procedures. It also allows for the design of a quality control system which automatically monitors those aspects of the measurement process which are the most likely to impact quality, including the characteristics of the individual sensors and the operator's actions.

i-STAT's quality control regimen has four aspects, resting on the foundation of a system design which reduces the opportunity for the type of error which traditional quality control regimens are designed to detect.

1. A series of automated on-line quality measurements that monitor the sensors, fluidics and instrumentation each time a test is performed
2. A series of automated on-line procedural checks monitors the user each time a test is performed
3. Liquid materials are used to verify the performance of a batch of cartridges when they are first received or when storage conditions are in question
4. Traditional quality control measurements verify the instrumentation using an independent device which simulates the characteristics of the electrochemical sensors in a way which stresses the performance characteristics of the instrumentation.

Similarities of the i-STAT Quality Control Regimen to Traditional Laboratory Quality Control Regimen

Although the more significant aspects of i-STAT's quality control regimen are the quality checks automatically performed with each unit-use cartridge, many principles of the quality control regimen are similar to traditional regimens.

Laboratory quality control methods are statistical. They assess the quality of the measurement process by intermittently inserting pseudosamples (controls) into the stream of samples being tested. The approach implicitly assumes that the elements of the measuring system persist from run to run so that the repeatability and accuracy of the measurement of patient samples can be predicted by the repeatability and accuracy of pseudosamples.

The i-STAT regimen uses an analogous approach to monitor the part of the testing process which persists from run to run - the handheld analyzer or Blood Analysis Module. An Electronic Simulator is analyzed on a sporadic basis and mimics the electrical characteristics of the signals produced by the sensors. The Electronic Simulator produces signals consistent with both very low and very high concentrations of each of the analytes. The analyzer or module causes the Electronic Simulator to change the signals via a control signal fed through the interconnect. The software in the analyzer and module measure these signals as it would measure signals from a cartridge. The software checks the measurements against predetermined thresholds and indicates their acceptability to the user via a PASS/FAIL message.

An important aspect of the Electronic Simulator is that it mimics the sensitive nature of the sensor's signals to ensure that adjacent input channels within the analyzer or module maintain the required degree of electrical isolation from each other to prevent "crosstalk" (see US Patent #5124661 for details). This cannot be achieved by the traditional internal self-consistency checks characteristic of modern microprocessor controlled instrumentation.

Comparison of this regimen to laboratory quality control procedures can seem confusing because it does not employ liquid control solutions. However the principle is the same in that the traditional intermittent quality control measurements are applied to the persistent part of the system. In the case of the i-STAT System, only the instrumentation is persistent so only this portion is tested with an external challenge.

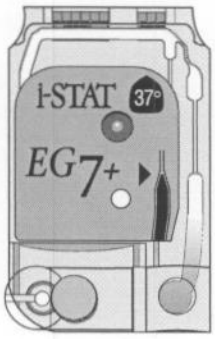
Further, use of an electronic quality control device has distinct quality advantages:

1. Non laboratory-trained individuals do not need to interpret control results because the analyzer and module software, expecting certain simulator signals, automates the interpretation. In comparison, many quality control regimens using liquid controls at the point of care are ineffective because an out of control result is easy to ignore.

2. Injecting signals directly into the analyzer or module allows very tight control limits to be set. Control limits using liquid controls at the point of care are generally very wide to allow for sensor-to-sensor variation.

The i-STAT Unit-Use Cartridge as an Element of Design Robustness for Point-of-Care Testing

The most important quality measure in the i-STAT System is that it is designed to reliably deliver quality results in the hands of individuals not trained in laboratory science. It addresses those aspects of the design in traditional laboratory based equipment and other point-of-care devices which detract from robustness in the hands of these individuals:



1. In the interest of making batch processing efficient, laboratory devices make extensive use of components which are exposed to each test sample (sensors, tubing, etc.). These devices must be continuously recalibrated as successive samples interact with these elements. Quality control regimens are designed to detect incorrect or required calibrations.

   All elements which are exposed to the test sample are unit use in the i-STAT system. Many of the out of control conditions which a laboratory quality control regimen is designed to catch simply do not exist.

   *Furthermore, the use of unit-use devices is directly related to the design of i-STAT's quality approach. Each test begins with fresh sensors and a fresh calibrant fluid. The response of the sensors' signals to the fresh calibrant fluid is well characterized from a large database of tests run in i-STAT's manufacturing facility. If the sensor signal is uncharacteristic due to mismanufacture, mishandling or misstorage, the handheld analyzer or Blood Analysis Module's software will suppress the result (displays "***").*

2. Many point-of-care devices require the non laboratory-trained user to interact directly with the sensing elements (paper strip technologies for example). Many Point-of-Care Coordinators rely heavily on the daily quality control regimen not only as a means for monitoring system performance, but more significantly, as a means for monitoring user proficiency.

   The analyzer controls all fluid motions in the i-STAT system. The calibrant and sample are brought to the sensors under instrument control so that the user does not directly impact on the quality of the analytical process and therefore cannot impinge on the quality of the results.

   Further, the analyzer uses a fluid sensor to electronically verify the proper flow of fluids within the cartridge on every run. This can easily be demonstrated by attempting to fool the system by putting in too much sample, too little sample, rerunning the same cartridge, introducing an air segment into the fluid segment, etc. The analyzer will flag these conditions and not deliver a result.

3. The design of some unit-use point-of-care devices can allow an entire batch of unit-use devices to be affected by a single event, for example by leaving a tube of paper strips open and exposed to a high humidity environment.

   With the i-STAT System, each unitized device is sealed in a separate foil pouch and has its own individual history. The only external factor which can create a shared history among cartridges is temperature. This is controlled by appropriately monitoring the storage environment.

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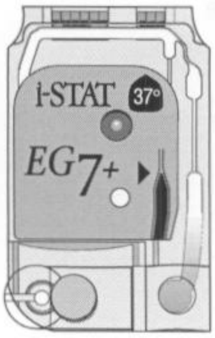
The Foundation of i-STAT's Quality Control Regimen - On-Line Tests

The fundamental backbone of i-STAT's quality regimen is the series of automatic checks performed **each time** a cartridge is run. The table below lists the key elements and operations of the i-STAT System that are verified each time a cartridge is used. For completeness, those operations which are qualified by the Electronic Simulator are also listed.



Unit-Use Cartridge	*When Verified*
Microfabricated Electrochemical Sensor Elements	
• verify sensors are present	every cartridge use
• verify sensor characteristics are consistent with expectations of a properly manufactured and maintained device (by testing calibration fluid)	every cartridge use
Calibration Fluid	
• verify fluid is present	every cartridge use
• verify fluid is delivered free of bubbles	every cartridge use
• verify fluid has proper concentration	every cartridge use
Fluidic System	
• verify sample holding chamber is sealed	every cartridge use
• verify fluid flowpaths are intact (no part of the Analyzer or module comes into direct contact with fluid)	every cartridge use
• verify waste chamber is not occluded	every cartridge use
Elements that Interact with the analyzer or Module	
• verify electrical contact pads (that allow access to sensor signals) are unoccluded	every cartridge use
• verify internal element of cartridge that allows the analyzer or module to control the release of calibration fluid over the sensors is functioning properly	every cartridge use
• verify internal element of cartridge that allows the analyzer or module to control the replacement of calibration fluid with sample is functioning properly	every cartridge use

HANDHELD ANALYZER OR BLOOD ANALYSIS MODULE

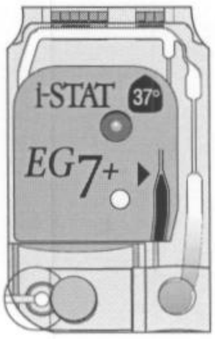
Motorized Mechanical System	
• verify electrical contact made with sensors on cartridge	every cartridge use
• verify ability to properly move calibration fluid	every cartridge use
• verify ability to properly move sample	every cartridge use

Electrical Measurement System

• verify voltage measuring system for potentiometric sensors	Electronic Simulator
• verify current measuring system for amperometric sensors	Electronic Simulator
• verify resistance measuring system for conductometric sensors	Electronic Simulator

Other

• verify internal self-consistency of electronic systems	every cartridge use
verify fluid flow using the conductivity sensor	every cartridge use
• verify function of transducers used for measuring barometric pressure	every cartridge use
• verify function of the thermistors used to set control chip temperature	Electronic Simulator



Operator Sample Handling / Cartridge Handling

• verify the cartridge inserted has not been previously used	every cartridge use
• verify the calibration pack has not prematurely ruptured	every cartridge use
• verify the electronic contact pads are dry and uncontaminated	every cartridge use
• verify the proper amount of sample was placed intothe sample chamber	every cartridge use
• verify the sample was properly positioned within the sample chamber	every cartridge use
• verify the sample is free of included bubbles	every cartridge use
• verify the sample is not clotted	every cartridge use
• verify the sample chamber is properly sealed with the snap closure	every cartridge use

VALIDATING THE PERFORMANCE OF THE i-STAT SYSTEM

Until recently, some regulations and laboratory accreditation standards specified the use of traditional quality control regimens, including the daily use of liquid "control" materials. As new technologies such as the i-STAT System have become available, the community has recognized the limitations of relying upon traditional regimens, prompting modifications of these standards accordingly.

The danger of denoting specific methods of achieving an effective quality control regimen has been recognized. Additionally, specific methods cannot anticipate future technological changes, so the responsibility of establishing and validating the quality system a laboratory employs has been placed on the laboratory director.

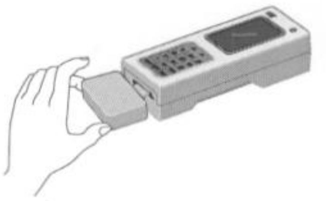
Quality control regimens should be established using information from the manufacturer and scientific literature. It is important to validate the performance of the i-STAT System and the recommended quality control regimen to develop personal confidence in our approach to the challenges of putting a diagnostic device in the hands of individuals untrained in laboratory science. Some of the regulatory and accreditation organizations recommend the daily use of liquid "control" materials for the first month of use, slowly stepping back the frequency as a database of performance information increases confidence levels. The number of lots of materials examined should also be considered when determining a validation protocol.

Verification of Newly Received Cartridges

1. Verify that the transit temperatures were satisfactory using the four window temperature indicator strip affixed to the cartridge boxes.
2. From each shipment of cartridges received, analyze multiple levels of i-STAT Controls using any verified Analyzer. See the section in the i-STAT System Manual that covers troubleshooting if results are outside expected ranges published in the control insert sheet.

Daily Procedure

1. Verify the performance of each Analyzer in the i-STAT System on site using the i-STAT Electronic Simulator. Quality tests at two signal levels are performed automatically by the simulator and a PASS/FAIL message indicates whether the Analyzer's measurements are within specifications. See Analyzer Troubleshooting in the event a FAIL message is displayed.
2. Verify that the cartridges stored in the refrigerator are within the expiration date printed on the boxes. Verify that the storage refrigerator did not exceed the temperature limits of 2 to 8ÞC (35 to 46ÞF).
3. Verify that the cartridges stored at room temperature are within the expiration date and that they have been out of the refrigerator less than two weeks.



Insert the Electronic Simulator into the analyzer with the "i" facing up. Do not touch the contact pads.

The analyzer will activate and identify the Electronic Simulator. Wait until the LCK prompt disappears from the display screen before removing the Electronic Simulator.

Results of the electronic test can be tracked on the Electronic Simulator Log found in this section. Electronic Simulator results are stored by the analyzer and can be transmitted to the Central Data Station.

EXTERNAL VS INTERNAL ELECTRONIC SIMULATOR

The external Electronic Simulator is a stable electronic device which is inserted into the cartridge port of the Analyzer to verify the electrical measurement as described in the paragraphs above.

The internal electronic simulator is a circuit in the Analyzer which, when enabled, performs the same functions as the external Electronic Simulator, eliminating the time required to locate and test each Analyzer.

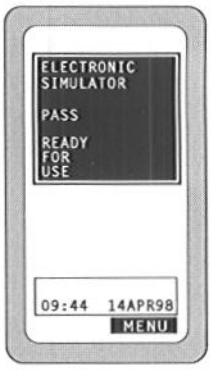
NOTE: The Analyzer Customization Profile Utility (customization utility) is used to enable the internal Electronic Simulator and determine its frequency. See the Technical Bulletin on the Analyzer Customization Profile for enabling this function. Without a Central Data Station, the internal Electronic Simulator cannot be enable and the external Electronic Simulator must be used.

When enabled, the internal Electronic Simulator test is triggered by inserting a cartridge. If the software detects that the specified time has elapsed since the last Electronic Simulator test (internal or external), it will automatically perform the internal test before the sample is tested, adding about 15–20 seconds to the testing cycle. With all Analyzers, a failed Simulator test stops the cycle, the "FAIL" Simulator result will be displayed on the screen, and the sample will not be analyzed. If the test passes, the cartridge cycle continues to completion and the cartridge results are presented to the user in the standard way.

The electronic documentation when using the internal Electronic Simulator is essentially the same as when using the external Electronic Simulator. The results of the Simulator test are stored as a distinct record in the Analyzer and can be downloaded to the Central Data Station.

ELECTRONIC SIMULATOR TEST FAIL

With both the internal and external Electronic Simulator, an Analyzer may occasionally fail a Simulator test even though it is in proper operating condition due to the extremely sensitive nature of the test.


ELECTRONIC
SIMULATOR
PASS
READY
FOR
USE
09:44 14APR98

If the analyzer is operating within specification limits, PASS will be displayed at the conclusion of the testing cycle. If the analyzer is not operating within specification limits, FAIL will be displayed along with one or more letters.

If using the external Electronic Simulator:

Run the test again and/or try another simulator as it is possible that the test will pass on a second try. The test can also fail if the external Electronic Simulator is malfunctioning such as after being dropped.

If using the internal Electronic Simulator:

The cartridge should be rerun to confirm the failure. The Analyzer's connector pins are in contact with the biosensor chips in the cartridge being tested when the internal Electronic Simulator test is being performed. The test can fail if the contact pads have been contaminated in some way.

- If **"QC lockout" is enabled:** Rerun the cartridge in the same Analyzer to ensure the FAIL was not due to a one-time spike of electrical noise. If the test fails again, rerun the cartridge in another Analyzer if immediately available. Note that the cartridge should not be run if there is more than a three minute delay from the time it is filled. When "QC Lockout" is enabled, the Analyzer will continue to perform the internal Electronic Simulator test each time a cartridge is inserted until the test (internal or external) passes.
- If **"QC lockout" is not enabled:** Rerun the cartridge in another Analyzer if immediately available. Note that the cartridge should not be run if there is more than a three minute delay from the time it is filled. When "QC Lockout" is not enabled, the Analyzer will run the next cartridge without performing the internal Electronic Simulator test until the specified time has elapsed.

If the cartridge fails in more than one Analyzer, use another cartridge. In all cases, an external Electronic Simulator can be used to verify proper performance of the Analyzer. Occasionally when an Analyzer is moved from a cold environment to a warm, humid environment, moisture may condense on the internal connector. An Analyzer in this condition will fail the electronic test and the failure code "L" will be displayed. Allow the Analyzer to sit for half an hour to allow the moisture to evaporate, then insert the Electronic Simulator again. If the Analyzer passes the second electronic test, continue using it. If the Analyzer fails a second time, record the letters displayed with the FAIL message and call i-STAT Technical Service.

CONTROL AND CALIBRATION VERIFICATION FLUIDS

Aqueous assayed control fluids are available from i-STAT Corporation for verifying the integrity of newly received cartridges. i-STAT Level 1, 2 and 3 Controls are formulated at three clinically relevant levels with known pH and with known concentrations of sodium, potassium, chloride, O_2, CO_2, ionized calcium, urea, glucose and creatinine. These solutions do not contain human serum or serum products.

A similar five level Calibration Verification Set is also available to verify the calibration of i-STAT cartridges throughout the reportable ranges for sodium, potassium, chloride, ionized calcium, pH, PCO_2, PO_2, urea, glucose and creatinine

Storage

i-STAT Level 1, 2 & 3 Controls and i-STAT Calibration Verification fluids are contained in 1.7mL glass ampules. Refrigerated storage at 2 to 8ÞC (35 to 36ÞF) should be maintained until the printed expiration date on the box and ampule labels. Controls and Calibration Verification fluids may also be stored at room temperature for up to 5 days (20 to 30ÞC or 68 to 86ÞF), however prolonged storage at temperatures greater than 30ÞC (86ÞF) may cause changes in the values of some analytes. Do not use beyond the expiration date on the box and ampule labels.

Directions for Use

Prior to testing cartridges that measure oxygen (G3+, EG6+ or EG7+), ampules should stand at room temperature a minimum of 4 hours before use. When testing other cartridges (G, Crea, E3+, EC4+, EC6+, 6+, or EC8+), ampules may be used once the fluid has reached room temperature, approximately 30 minutes for individual ampules. For best results, ampules, cartridges and Analyzers should be at the same temperature. When using cartridges that contain sensors for measuring ionized calcium, pH, PCO_2 or PO_2 (G3+, EG6+, EG7+, EC6+ or EC8+), a separate ampule must be used for each cartridge being tested; if these sensors are not present (ie. the 6+ cartridge), the contents of one ampule may be used to fill more than one cartridge as long as the cartridges are filled and inserted into an Analyzer within 10 minutes of opening the ampule.

NOTE:

Since aqueous based solutions such as control or calibration verification fluids lack the buffering capabilities of whole blood, the transfer process from vial to cartridge must be more expedient than with a patient sample.

Immediately before use, shake the ampule vigorously for 5 to 10 seconds to equilibrate the liquid and gas phases. To shake, hold the ampule at the tip and bottom with forefinger and thumb to minimize increasing the temperature of the solution. If necessary, tap the tip of the ampule to send solution back into the bottom section of the ampule. Protect fingers with gauze, tissue, or glove, or use an ampule breaker to snap off the tip of the ampule at the neck. Immediately transfer the solution from the ampule into a capillary tube or syringe, and then immediately transfer the solution into a cartridge. Immediately seal the cartridge and insert it into an Analyzer—it is important not to expose the solution to room air since this will alter the results.

When using a capillary tube (fresh capillary tubes with sufficient fill capacity are recommended), fill from the bottom of the ampule. Avoid drawing solution from the surface by covering the far end of the tube as it is inserted into the ampule. Once the open end of the tube rests at the bottom of the ampule, uncover the other end to allow filling by capillary action.

When using a syringe (fresh 1cc or 3cc sterile syringes with 20 gauge or larger needles are recommended), slowly draw approximately 1mL of solution from the bottom of the ampule. If air is trapped between the leading edge of the solution and the plunger, do not invert the syringe to expel it; this will not affect solution near the front of the syringe. If air bubbles are continually drawn into the syringe, or if a bubble is trapped near the tip of the syringe, discard the ampule and syringe and use a fresh ampule and syringe. Expel one or two drops from the syringe before filling the cartridge.

Do not use solution left in a syringe, ampule or capillary tube for additional testing of cartridges that contain sensors for ionized calcium, pH, PCO_2 or PO_2. However, cartridges without these sensors may be tested with remaining fluids if within 10 minutes of opening the ampule.

Control Target Values and Expected Ranges

Target values (determined by testing multiple ampules of each level using multiple lots of i-STAT cartridges with i-STAT handheld Analyzers that have passed the Electronic Simulator test) are printed on an insert included with each box of control ampules. The ranges displayed represent the maximum deviation expected when controls and cartridges are performing properly. Should results outside the ranges be obtained, refer to the Cartridge Troubleshooting section in this manual.

Always be sure that the lot number printed on the insert matches the lot number on the label of the ampule in use, and that the software revision above the table matches the software revision in the Analyzer (check the status page).

NOTE: Target Values are specific to the i-STAT System; results obtained from these aqueous controls with other methods may differ due to sample matrix effects

Calibration Verification Calculations and Acceptable Criteria

Target values (determined by testing multiple ampules of each level using multiple lots of i-STAT cartridges with i-STAT handheld analyzers that have passed the Electronic Simulator test) and acceptable ranges for the means of 3 replicates are printed on an insert included with each Calibration Verification set. Calibration throughout the reportable range of each analyte is verified if each average value falls within the corresponding acceptable range. To calculate the average value, add the three results obtained for each test in each level and divide by three. If an average value is not in range, inspect the results for a statistical outlier. If a result is determined to be an outlier, test a fourth cartridge using the fourth ampule included in the Calibration Verification set, and recalculate the average value after replacing the outlier with the new result. If the average value is still outside the acceptable range or if there is more than 1 outlier for every 20 sets of results, troubleshooting may be required.

Always be sure that the lot number printed on the insert matches the lot number on the label of the ampule in use, and that the software revision above the table matches the software revision in the analyzer (check the status page).

i-STAT System QC Log: Incoming QC

Cartridge Type:________ **Lot No.:**________ **Rec'd Date:**________ **Exp. Date:**________ **Quat:** ________ **Temp. Strip*:** ________

Control Name: ________ **Level:** ________ **Lot No.:**________ **Exp. Date:** ________

TEST	TEST	TEST	TEST	TEST	TEST	TEST	TEST
RANGE	RANGE	RANGE	RANGE	RANGE	RANGE	RANGE	RANGE

Control Name: ________ **Level:** ________ **Lot No.:**________ **Exp. Date:** ________

TEST	TEST	TEST	TEST	TEST	TEST	TEST	TEST
RANGE	RANGE	RANGE	RANGE	RANGE	RANGE	RANGE	RANGE

Control Name: ________ **Level:** ________ **Lot No.:**________ **Exp. Date:** ________

TEST	TEST	TEST	TEST	TEST	TEST	TEST	TEST
RANGE	RANGE	RANGE	RANGE	RANGE	RANGE	RANGE	RANGE

Control Name: ________ **Level:** ________ **Lot No.:**________ **Exp. Date:** ________

TEST	TEST	TEST	TEST	TEST	TEST	TEST	TEST
RANGE	RANGE	RANGE	RANGE	RANGE	RANGE	RANGE	RANGE

Lot/Shipment accepted by: ________ **Date:**________

* OK or indicate blue window(s)

i-STAT System QC Log: Expiration Date and Storage Conditions

				REFRIGERATED 2 TO 8°C (35 TO 46°F)			ROOM TEMPERATURE 18 TO 30°C (64 TO 86°F)				
DATE	LOCATION	CARTRIDGE TYPE	LOT #	QTY	EXP DATE	TEMP	QTY	EXP DATE	TEMP	ACTIONS	INSP.

i-STAT System Electronic Simulator Log

DATE	TIME	OPERATOR	ANALYZER (SERIAL NUMBER)	ELECTRONIC SIMULATOR (SERIAL NUMBER)	PASS/FAIL

If analyzer fails, record letters(s) and call i-STAT Technical Service. Record action taken on Electronic Simulator Action Log.

i-STAT System Electronic Simulator Action Log

DATE	OPERATOR	ANALYZER (SERIAL NUMBER)	FAILED (LETTERS)	ACTION	PASS/FAIL

ROUTINE CARE, TROUBLESHOOTING & TECHNICAL INFORMATION

6

If a problem cannot be resolved by the procedures described in this section, call the i-STAT Assistance Center at 1-800-366-8020. Have the following pertinent information available for review with the i-STAT Technical Service representative:

- Brief description of problem
- Serial number of component(s)
- Lot number(s) of cartridges in use
- Lot number(s) of controls in use
- Results of controls
- Uses count from Status page
- Battery voltage from Status page
- Results of last Electronic Simulator test
- Electronic Simulator serial number
- Displayed message and code #
- Customer number

ROUTINE CARE OF THE HANDHELD ANALYZER

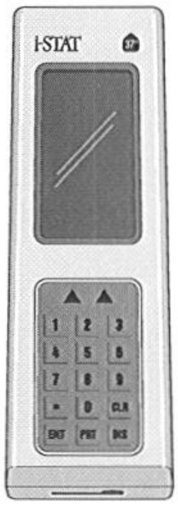
Cleaning and Decontaminating

If the analyzer is placed on a wet surface or if any liquid is spilled onto it, dry the analyzer immediately. If liquid enters the electronics compartment, the battery compartment, or the cartridge port, the analyzer may be damaged.

Clean the display screen with a soft dry tissue. Clean the case using a gauze pad moistened with a mild non-abrasive cleaner, detergent, soap and water, or alcohol; rinse using another gauze pad moistened with water and dry.

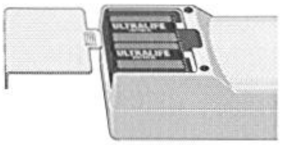
Decontaminate the analyzer whenever a specimen is spilled onto the analyzer or if the analyzer is to be returned to i-STAT for repair. Wear gloves while performing the following procedure:

1. Prepare a 1:10 solution of household bleach by mixing one part of bleach with nine parts of tap water. This solution will maintain its germicidal action for a week.
2. Soak a few gauze pads in the bleach solution. Before use, squeeze the pads to remove excess solution.
3. Soften, then remove any dried blood with one or two of the gauze pads soaked in the bleach solution. Avoid scraping dried blood as contaminated particles may become airborne.
4. Clean the entire surface of the analyzer twice with gauze pads soaked in the bleach solution.
5. Rinse the surface of the analyzer with gauze pads moistened with tap water and dry.
6. If the analyzer is to be shipped, place it in a plastic bag.



CAUTION:

Do not immerse the analyzer.



Battery compartment opening.

CAUTION:

Always use two 9 volt lithium batteries. Inaccurate messages may be displayed if other types of batteries are used. Do not insert a single battery, particularly so that it connects with the two center holes: this could cause damage to the analyzer and will short circuit the battery.

Replacing the Batteries

Wait until any test in progress is completed before replacing the batteries or results will be lost. Stored results will not be lost when replacing the batteries.

Procedure:

1. Place the analyzer upside down and slide the battery compartment door off.
2. Remove the old batteries. Orient the + and - poles of the new batteries with the + and - labels in the battery compartment and slide the new batteries into place.
3. Put the battery compartment door back into place.

Checking the Temperature

Place the analyzer in a room with a calibrated thermometer suspended near the analyzer and away from air currents for one hour. Then press the display key and access the Status page. The temperature reading should be ± 1°C of the thermometer's reading.

Updating the Software

Whenever new tests and features become available the analyzer software requires updating. Complete instructions for installing new software will be sent with updates.

HANDHELD ANALYZER TROUBLESHOOTING

Note: Refer to the appropriate Hewlett-Packard user documentation on troubleshooting procedures for the HP Blood Analysis Module.

No Display

If the display screen remains blank, either after a cartridge has been properly inserted or after the display key has been pressed, the batteries should be replaced.

"LCK" Not Removed

Normally the analyzer will reset and release the cartridge after the testing cycle is completed. If the analyzer cannot reset, the LCK prompt will remain on the screen.

Wait until the analyzer deactivates (display screen blank) and press the display key. The LCK prompt and results will be displayed. The analyzer will attempt to reset. If the LCK prompt disappears from the screen, remove the cartridge and continue to use the analyzer. If the LCK prompt does not disappear, do not attempt to remove the cartridge. Call Technical Service.

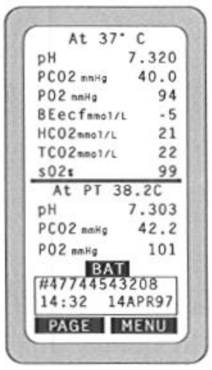
49

Analyzer Prompts

The analyzer prompts the operator when a certain action is required. There are two types of prompts.

- Simple input prompts, such Repeat #, appear in the operator and patient identification number box.
- Alert prompts are displayed in a reverse video box above the operator and patient identification number box. The alert prompts are described below.

LCK LCK appears on the display screen during the testing cycle to indicate that the cartridge or Electronic Simulator is locked in the analyzer and should not be removed. A cartridge or simulator should be removed only after the LCK prompt disappears from the screen.



```
   At 37° C
pH              7.320
PCO2 mmHg        40.0
PO2 mmHg           94
BEecf mmol/L       -5
HCO2 mmol/L        21
TCO2 mmol/L        22
sO2 %              99
   At PT 38.2C
pH              7.303
PCO2 mmHg        42.2
PO2 mmHg          101
        BAT
#47744543208
14:32    14APR97
PAGE      MENU
```

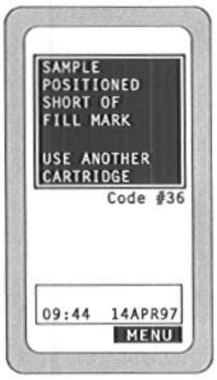
BAT BAT will appear when the battery voltage drops to 7.4. At this point there is sufficient power to test approximately 50 more cartridges before a DEAD BATTERIES message is displayed.

SIM SIM will appear if the analyzer has not been tested with an Electronic Simulator in the last 8 hours and when an electronic error occurs after a testing cycle is completed or after the display key is pressed. In the later case, the displayed results are not affected. When the SIM prompt appears, check the analyzer using the Electronic Simulator. If the test passes, continue to use the analyzer. If the test fails, call Technical Service.

SFT SFT will appear 15 days before the expiration date of the analyzer's software. Contact i-STAT Technical Service if new software has not been received or if a software update has not been scheduled.

Analyzer Messages and Quality Check Codes

If a problem is detected during a testing cycle, the cycle will be stopped and a message box will appear on the display screen. The messages will identify the problem and indicate the next step to be taken. If the analyzer deactivates before the detected problem is addressed, the message box will reappear the next time the display key is pressed. Below the message box is a code #. This number may be helpful to i-STAT Technical Service if a problem cannot be resolved.

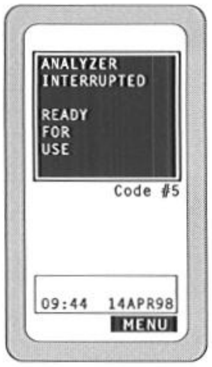


```
SAMPLE
POSITIONED
SHORT OF
FILL MARK

USE ANOTHER
CARTRIDGE
          Code #36

09:44    14APR97
            MENU
```

Cause *Message on Display*	Action
The following messages usually indicate a condition related to the environment or the state of the analyzer. These conditions are usually benign and go away after the next cartridge or an Electronic Simulator is inserted, or after the offending condition is corrected.	
Dead Batteries *Replace Batteries*	Replace batteries. The analyzer does not have enough power to complete the testing cycle.
Temperature Out of Range *Check Status Page*	The analyzer is too warm or too cool because it has just been moved from or is now in a room that is too warm or too cool.

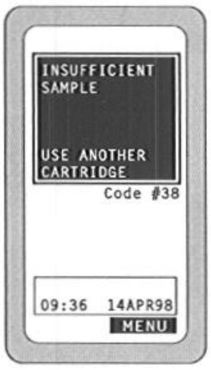


Cause *Message on Display*	Action
New Software Installed *Use Electronic Simulator*	This is a normal response from analyzer after installation of new software if Electronic Simulator has not been run.
Analyzer Interrupted *Use Another Cartridge*	The analyzer has detected that the last cartridge run was not completed. This can happen if battery voltage is low, or if batteries were removed or or making poor contact while a cartridge was still in the analyzer. Check that batteries are inserted properly and seated well in the analyzer; check battery voltage on Status Page and replace batteries if low. Run Electronic Simulator—this should take the system through a "run" which will be completed properly.
Analyzer Interrupted *Ready for Use*	The analyzer is unable to refresh the display. This can happen if power is interrupted before the analyzer powers itself down. Check that batteries are inserted properly and seated well in analyzer; check battery voltage on Status Page. Run Electronic Simulator.
Batteries Changed *Ready for Use*	The analyzer detects a "jump" in battery voltage—no action is necessary.
Temperature in Range *Ready for Use*	This message occurs when the analyzer temperature is within operating range after a temperature out of range condition has been detected.
Date Invalid *Check Clock on Status Page*	The analyzer detects an invalid date—one that is earlier than the release date or past the expiration date of the software. Check and reset the date on the Status Page.
Invalid or Expired CLEW *See Manual*	The CLEW standardization set is either expired, missing, or corrupted. Download CLEW standardization set again.

The following conditions usually indicates an error condition relating in some way to the cartridge or fluid movement within a cartridge. These conditions can be operator or sample related. In most cases a new cartridge must be used. If a condition persists, especially if isolated to one analyzer, there may be an analyzer problem.

Cartridge Error *Use Another Cartridge*	These codes can all be caused by a variety of reasons including ample related problems, users, cartridges, or analyzers. Single or sporadic errors are most likely a sample-related problem (an interferent), an aberrant cartridge, or a user-induced situation such as touching cartridge contacts, pressing on center of cartridge, or bubbles in the sample ("frothy" samples). A problem with the analyzer is possible if an quality check code occurs repeatedly on one particular analyzer.
Cartridge Preburst *Use Another Cartridge*	This code indicates that the analyzer detected fluid on the sensors before it should have. Possible causes: poor storage conditions of cartridges (frozen or too warm), or mishandling of cartridges (putting pressure in the center of the cartridge). Try another cartridge.

Cause *Message on Display*	Action
Unable to Position Sample	The analyzer did not detect movement of sample across the sensors. This could be due to not closing the snap closure on the cartridge, to a clot in the sample preventing movement of the sample, or to an aberrant cartridge.
Sample Positioned Short of Fill Mark *Use Another Cartridge*	The cartridge was underfilled. The sample must reach the fillmark. Try another cartridge
Sample Positioned Beyond Fill Mark *Use Another Cartridge*	The cartridge was overfilled. The sample was past the fill mark. Try another cartridge.
Insufficient Sample *Use Another Cartridge*	This is most likely due to insufficient sample in the sample well of the cartridge, but will also be caused by bubbles in the sample. Try another cartridge.
Cartridge Not Inserted Properly *Reinsert Cartridge*	The code indicates the cartridge or external Electronic Simulator may not be pushed in all the way. Reinsert the cartridge or Electronic Simulator. If problem is recurrent and/or the user is certain the cartridge or Simulator is properly inserted, it may indicate an instrument problem. Call i-STAT Technical Services.


INSUFFICIENT SAMPLE

USE ANOTHER CARTRIDGE

Code #38

09:36 14APR98

The following conditions are related to electronic or mechanical failures in the analyzer.

Analyzer Error *Use Electronic Simulator*	The analyzer usually recovers from these errors when the Electronic Simulator is run. This error can occur if the cartridge or Electronic Simulator was "angled" when inserted. Push cartridge or Simulator straight through the cartridge port. This error can also occur if the Electronic Simulator is malfunctioning (has it been dropped?). Try another Simulator. If the analyzer passes the Electronic Simulator check, continue to use it. If not, or if the quality check code is recurrent, the analyzer may need repair. Call i-STAT Technical Services.
Analyzer Error *See Manual*	These are mechanical or electronic failures from which the analyzer may not be able to recover. Use an external Electronic Simulator twice and use a cartridge with sample or control solution. If an error conditions occurs, call i-STAT Technical Services. If not, continue to use the analyzer.
Cartridge Type Not Recognized *Use Another Cartridge*	This error could be due to use of a cartridge type which is not compatible with the version of software in the analyzer. If this is a new cartridge type being used, call i-STAT Technical Services for an upgrade. If the cartridge type has been used before, an analyzer problem is indicated and the analyzer may need repair. Call i-STAT Technical Services.

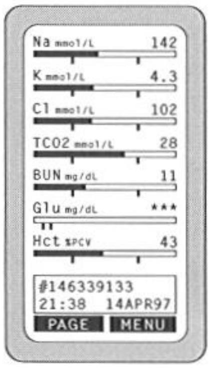
CARTRIDGE TROUBLESHOOTING

"***" Instead of Results

Stars appear in place of results if the analyzer detects that the sensor's signal is uncharacteristic. Cartridges that have been stored improperly may show "***" instead of results. Check the supply of cartridges in use with a control solution. If the control result(s) are starred, discontinue use of this supply of cartridges. If the control results are in range there may be a problem with the specimen. Aged specimens may contain products of metabolism that can interfere with the test(s). A fresh sample should be tested. If the stars reappear there may be an interferent present. When flags occur, the specimen must be tested by another type of analyzer in order to obtain results.

Control Out-of-Range

When a result for a control solution is outside of the expected range, that supply of cartridges should not be used until the cause is identified and corrected:



```
Na mmol/L      142
K mmol/L       4.3
Cl mmol/L      102
TCO2 mmol/L     28
BUN mg/dL       11
Glu mg/dL      ***
Hct %PCV        43
#146339133
21:38   14APR97
```

Check Expiration	Do not use beyond the expiration dates on the labels.
Check Storage Conditions	Check that the control and cartridges have been stored according to directions.
Check analyzer	Use the Electronic Simulator as described in the section of this manual that discusses quality control to ensure that the analyzer is working properly.
Repeat Same Lots	Repeat the control test using the same source of control and cartridge. Ensure that ampule controls and cartridges are at room temperature and the directions for use are followed precisely. If the control result is now in-range, document the corrective action as "repeat test in-range." If the control is still out-of-range, continue with the next step.
Use New Source of Control	Test a new vial or ampule of control from the same lot number. If the control result is now in-range, document the corrective action as "fresh control". If the control is still out-of-range, continue with the next step.
Use New Source of Cartridge	To identify the source of the cartridge problem, test cartridges in the following order: 1. *New box, same lot number.* If the control result is now in-range, document the corrective action as "fresh box of cartridges, possible shipping or storage problem." 2. *New box, same lot number, new shipment.* If the control result is now in-range, document the corrective action as "new shipment, same lot of cartridges, possible shipping or storage problem."

3. *New lot number.* If the control result is now in-range, document the corrective action as "new lot of cartridges, possible cartridge problem." Report this finding to i-STAT Technical Service. If the control result is still out-of-range, call i-STAT Technical Service.

ROUTINE CARE OF THE PORTABLE PRINTER

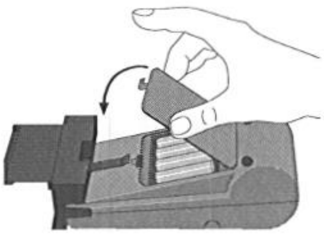
Replacing the Batteries

Install fresh batteries when any of the following conditions occur:

- Print contrast is uncomfortably low, even when the print control is set to highest contrast.
- Printing slows because the print head moves across the paper at a much slower speed. (When a large amount of information—more than 200 characters—is transmitted by the analyzer, printing slows because the printer pauses momentarily before printing each new line. However, the print head moves across the paper at normal speed. This is not a symptom of low batteries.)
- Printing halts before all information on a line has been printed.
- Battery condition index printed at the end of the self test is 1 or 0.

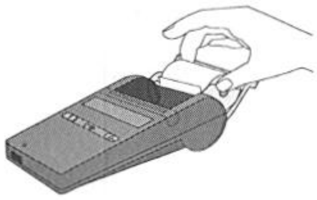
Use four 1.5 volt alkaline AA batteries. Remove battery compartment door.

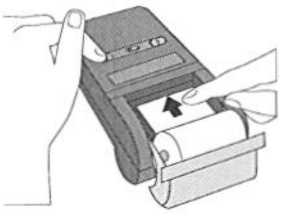
Install fresh batteries as shown. Replace battery compartment door.



Loading Paper

Do not operate printer without paper. Position paper in door as shown at right. Make sure leading edge of paper is cut evenly. While pushing paper into slot, hold down the paper advance switch until paper emerges. If paper jams, pull backwards very slowly. Place paper in compartment and close door. For best results, use the black-printing thermal paper supplied by i-STAT. Do not pull on paper; use the paper advance switch, and do not pull paper backward through printer. Do not run paper to end of roll if paper is attached to its inner core *(the paper supplied by i-STAT is not attached).*



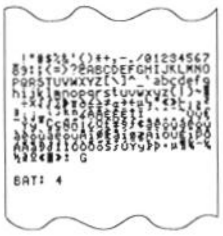


Self-Test and Battery Condition

If the printer is not operating properly, run the self-test. If the printer fails the self-test, rerun the test to verify the results. If the printer fails again, it requires service. The self-test can be run using the optional AC adapter; however, the battery condition index will not be accurate. To test the battery condition, disconnect AC adapter, turn off printer, and then hold down the paper advance indicator while turning the printer on, then release.

The battery condition index is a number from 0 to 5 (0,1 = low, 4,5 = high) that describes how much useful battery life remains. Regardless of the battery condition index, install new batteries when any of the symptoms of low batteries appear. If the printer is to be operated from batteries without interruption for an extended period of time, it is recommended that new batteries be installed before the index has dropped to 1.

SELF-TEST



```
 !"#$%&'()*+,-./01234567
89:;<=>?@ABCDEFGHIJKLMNO
PQRSTUVWXYZ[\]^_`abcdefg
hijklmnopqrstuvwxyz{|}~

BAT: 4
```

Controlling Printhead

If the printer is turned off while it is printing, the print head may stop in the middle of a line. To return the printhead to the left side of the paper, turn the printer on, then off. Leaving the print head in the middle of a line causes temporary lightening of characters in that column; continued printing restores the print contrast in that position.

Incorrect Character

A hatched-box character is printed if the printer detects incorrect data due to interference with or interruption of the stream of incoming information. Common causes for incorrect data are improper positioning of the printer with respect to the analyzer, obstruction of the infrared beam, or interference from another infrared source. Occasionally, the printer will print hatched-box characters when the analyzer is transmitting to the Central Data Station.

Potential for Radio/TV Interference

The printer generates and uses radio frequency energy and may cause interference to radio and television reception. The unmodified printer has been tested and found to comply with the limits for a Class B computing device in accordance with the specifications in Subpart J of Part 15 of FCC Rules, which are designed to provide reasonable protection against such interference in a residential installation. However, there is no guarantee that interference will not occur in a particular installation. In the unlikely event that there is interference to radio or television reception (which can be determined by turning the printer off and on, disconnecting the AC adapter, or removing the batteries), correct the interference by one or more of the following measures:

- Relocate the product with respect to the receiver.

- Plug the AC adapter into an outlet on a different branch line than the receiver.

PORTABLE PRINTER TROUBLESHOOTING

Not Printing

If the power-on indicator light is not lit, turn the printer on by moving the off-on switch to the right. If the switch is in the on (|) position, press the paper advance switch to reactivate the printer. If the indicator light does not light, change the batteries.

If the power-on indicator light is lit, the most recent set of test results cannot be printed unless patient identification number is entered or actively bypassed by pressing the ENT key twice. If the identification numbers have been entered, reseat analyzer in cradle with the analyzer's LED facing the IR Interface's receiver.

Stops Printing

If the power-on indicator light goes out, change batteries as described earlier. If the power-on indicator light is lit, do not lift the analyzer out of cradle until printing is completed.

Light Print

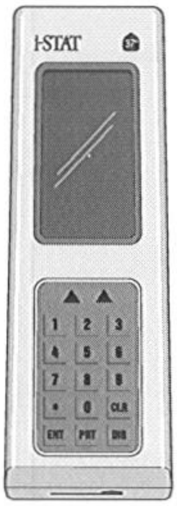
Move Print Contrast switch to right. If the switch is all the way to right, change the batteries as described earlier.

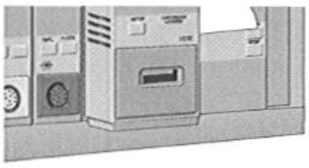
Garbled Print, Missing Characters or Symbols

If the analyzer is moved (lifted out of the cradle momentarily) while the printer is still printing, the printed information may be garbled, may be missing letters and numbers, or may include hatched box symbols. If the cradle is not used to align the printer and analyzer, other infrared signals, including those from other analyzers, can interfere with the transmission. Occasionally the printer will print hatched box symbols when the analyzer transmits to the Central Data Station.

THEORY 7

ANALYZER FUNCTIONS





The i-STAT handheld analyzer and Hewlett-Packard Blood Analysis Module are microprocessor-controlled electromechanical instruments which:

- Identify the cartridge type
- Control the flow of fluids within the cartridges
- Apply electrical signals to certain types of sensors within the cartridges
- Control the temperature of the cartridge at 37ÞC *(where applicable)*
- Measure electrical signals generated by the sensors
- Measure the barometric pressure of the surrounding environment *(where applicable)*
- Calculate concentrations of analytes using the generated electrical signals
- Display the results in numerical values and on bar graphs *(where applicable)*
- Communicate the results to a printer and computer
- Sense and communicate operational errors
- Maintain an internal clock/calendar
- Store all test records and Electronic Simulator results *(handheld analyzer only)*

Microprocessor System

The microprocessor control system manages all functions of the analyzer. It accesses three types of memory storage devices. A "FLASH" EEPROM module stores the software program in the analyzer. The RAM, which is backed up by an internal lithium battery, is used for temporary storage of sensor signals measured during operation and for storage of test records. Another EEPROM stores factory calibration information, the instrument serial number and a cumulative count of uses. Neither of the EEPROMs rely on the lithium battery for maintaining information.

Sensor Interface

Electrical signals from the sensors are conducted from the contact pads on the cartridge, through the internal connector in the analyzer, to the sensor interface circuit board. These circuits amplify the signals from the sensors so that they can be further processed by the main electronic circuit board.

Four signals are relayed to the main electronic circuit board from the sensor interface circuit board:

- A multiplexed potentiometric signal line
- A multiplexed amperometric signal line
- An AC fluid conductivity signal
- A digital identification code to identify the type of cartridge being inserted into the analyzer

Mechanical System

A single DC gearmotor drives mechanical system components:

- An electrical interconnecting system which brings the analyzer's electrical internal connector into contact with the contact pads on the cartridge
- A calibrant delivery system
- A sample delivery system
- A thermal control interconnectivity system which brings the analyzer's thermal controller into contact with heater elements on the back of cartridges

In addition, a latching mechanism locks the cartridge in place upon insertion.

Analog-to-Digital Conversion

An analog-to-digital convertor converts all analog signals into digital form so that the microprocessor can perform mathematical calculations on the signals. An analog signal multiplexer makes it possible for the microprocessor to measure eight different types of analog signals:

- The potentiometric signals from the sensor interface circuit
- The amperometric signals from the sensor interface circuit
- A DC conductivity signal
- The battery voltage
- A thermistor signal representing the internal temperature of the analyzer
- A motor feedback signal used to control the speed of the mechanical motion
- Cartridge temperature signals used to control the cartridge temperature to 37ÞC
- A pressure transducer signal representing the barometric pressure of the environment

Analog Control Signals

The analyzer creates and applies two types of signals to the sensors: a digital-to-analog convertor generates a voltage which is applied to amperometric sensors, and the AC conductivity circuit generates an AC excitation signal which is applied to the conductivity sensors. The digital-to-analog convertor also provides voltages to the motor driver circuit.

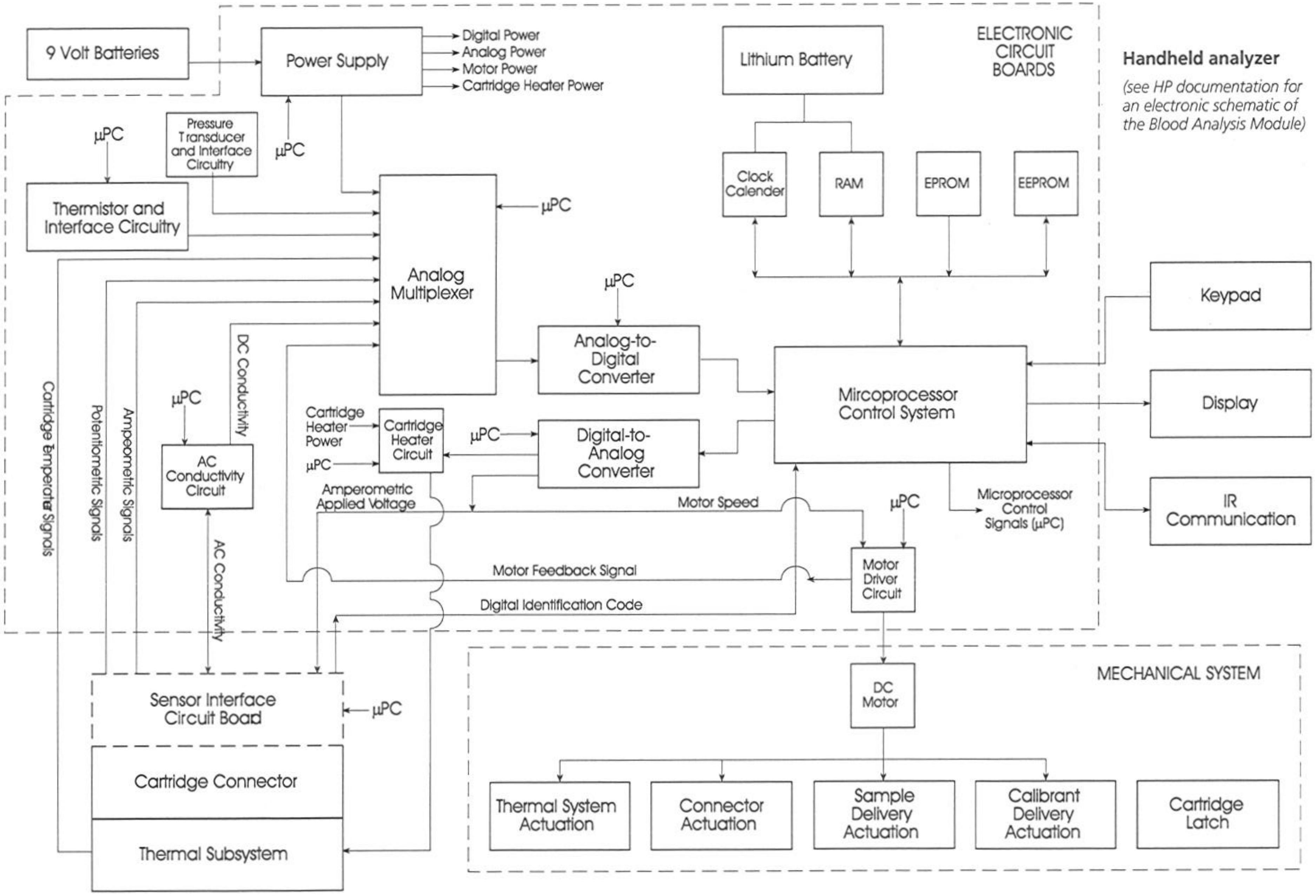
Operator Interface

The microprocessor control system coordinates the reading of information input by the user, the writing of information onto the display, and the communication of results. With the handheld analyzer, the IR link uses a communication protocol compatible with the Hewlett-Packard thermal printer available from i-STAT, and a faster protocol that allows communication to the Central Data Station.

The microprocessor control system also communicates with a clock/calendar circuit allowing the operator to set and read the time and date. The clock/calendar circuit is backed up by a lithium battery.

Handheld analyzer

(see HP documentation for an electronic schematic of the Blood Analysis Module)

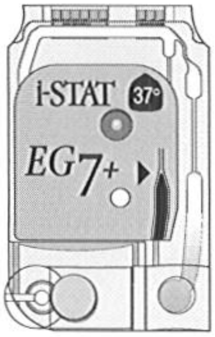

9 Volt Batteries
Power Supply
Digital Power
Analog Power
Motor Power
Cartridge Heater Power
µPC
Pressure Transducer and Interface Circuitry
Thermistor and Interface Circuitry
Analog Multiplexer
Analog-to-Digital Converter
Digital-to-Analog Converter
Lithium Battery
ELECTRONIC CIRCUIT BOARDS
Clock Calender
RAM
EPROM
EEPROM
Mircoprocessor Control System
Keypad
Display
IR Communication
Microprocessor Control Signals (µPC)
Cartridge Heater Power
Cartridge Heater Circuit
Amperometric Applied Voltage
Motor Speed
Motor Feedback Signal
Digital Identification Code
Motor Driver Circuit
DC Conductivity
AC Conductivity Circuit
AC Conductivity
Ampeometric Signals
Potentiometric Signals
Cartridge Temperatur Signals
Sensor Interface Circuit Board
Cartridge Connector
Thermal Subsystem
MECHANICAL SYSTEM
DC Motor
Thermal System Actuation
Connector Actuation
Sample Delivery Actuation
Calibrant Delivery Actuation
Cartridge Latch

ELECTROCHEMICAL MEASUREMENTS

Sensors

The general term "sensor" is used to refer to the three types of electrodes incorporated into the cartridges:

- Potentiometric
- Amperometric
- Conductometric



Sensors are thin film electrodes microfabricated onto silicon chips. Sensing functionality is imparted to each electrode by a number of chemically sensitive films coated over the active region of the electrodes.

Method

Measurements are performed on undiluted specimens. Undiluted methods are also called direct methods while methods requiring dilution of the sample are called indirect methods.

It is known that direct methods read up to 7% higher than indirect methods for electrolytes because of the excluded volume occupied by plasma protein and lipids. Typically, however, the elevation of results is less than the full 7% because some of the analyte is bound to protein and other ions, and is not assayed by direct methods. Indirect methods measure the total molar concentration of analyte per unit volume of plasma. Direct methods measure the total molar activity of analyte (apparent or free ion activity) per unit volume of plasma water. It is understood that the direct method result is the clinically significant result for electrolytes, and when there is disagreement between methods, such as when the patient has abnormal total protein or lipid levels, it is due to an interference on the indirect method.

At normal levels of protein and lipids the systematic offset between methods is often corrected for in commercial direct measuring instruments so that the normal ranges for all instruments are in agreement. Sensor outputs have been set so that normal ranges are in agreement with indirect reference methods at normal levels of total protein and lipids.

Direct measurement of hematocrit by conductometric technique gives a result related to the nonconducting excluded volume fraction of the sample fluid. Red blood cell volume is the predominant component of the nonconducting volume, but proteins, lipids, and white blood cells also contribute. Elevated hematocrit readings are expected at abnormally elevated levels of these components. Decreased hematocrit readings are expected at abnormally low levels of protein, such as found in samples taken from patients on perfusion pumps.

Osmotic imbalance causes a discrepancy between direct (conductometric, spun) and indirect (Coulter) measurements, because of variation in mean cell volume in vivo.

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Potentiometric Measurements

Potentiometry is the measurement of the difference in potential that exists between an indicator electrode and a reference electrode. Ion-selective electrodes (ISE) are examples of potentiometric systems. The indicator electrode is designed to be sensitive to a particular ion in a solution. In cases where other ions are sensed by the system, selectivity coefficients can be used to correct for this interference. An enzyme can be added to an ISE to produce ions from other analytes.

The Nernst Equation

The Nernst equation relates the measured potential to the activity of the ion being measured.

$E = E° + RT/nF \ln a$

Where E is the potential, E° is a constant dependent on the electrode/sensor system, R is the gas constant, T is the absolute temperature, F is Faraday's constant and n is the valance or charge, either positive or negative, for the ion being measured, and a is the activity of that ion.

The Nernst equation can be rewritten as:

$E = E° + S \log a$

Where S replaces the constant terms which define the slope of the sensor. The slope is the change in millivolts per tenfold change in activity. For a positively charged monovalent ion, the theoretical slope would be 59.16mV at 25°C.

When the potential for a calibrant, with known activity, and a sample are measured, the activity of the sample can be calculated from

$E_{sample} - E_{calibrant} = S\log(a_{sample}/a_{calibrant})$

Complex solutions such as blood, deviate slightly from Nernstian behavior due to interfering ions and matrix effects which result in junction potentials. By including selectivity coefficients in the Nernst equation (Nikolsky equation) these effects can be minimized. By characterizing the reference electrode in different solutions, effects of matrix on the reference junction potential can also be minimized.

Activity Versus Concentration

Ion-selective electrodes measure activity rather than concentration. Activity (a) is related to concentration (c) though the activity coefficient (γ) : $a = \gamma c$.

While ion activities, which reflect free rather than total ion concentrations, are physiologically important, activity values are converted to conventional concentration units so that values obtained by direct ISE can be compared to values obtained from indirect (diluted) ISE methods which have activity coefficients close to unity or one, and to flame photometric, atomic absorption and titration methods, all of which measure total ion concentration.

Amperometric Measurement

In amperometric measurements, a potential is applied to the measuring electrode while current generated by the oxidation or reduction reactions in the test system is measured. The current generated is directly proportional to the concentration of the analyte. Concentration can be calculated using: 1) the known value of the analyte in the calibrant; 2) the measured current generated by the analyte in the calibrant; and 3) the measured current generated by the analyte in the test solution.

Conductometric Measurement

The conductometric measurement involves the application of an alternating current to the test solution. In aqueous solutions conductivity is dependent upon the concentration of electrolytes, with an increase in electrolytes causing an increase in conductivity. In whole blood, the plasma conducts electricity while the cellular constituents, red and white blood cells and platelets, do not. As the number of cells per unit volume of plasma increases, the conductivity of the sample decreases. Cell concentration can be calculated using 1) the known electrolyte concentration of the calibrant; 2) the measured electrolyte concentration of the sample; 3) the measured conductivity of the calibrant; and 4) the measured conductivity of the test solution.

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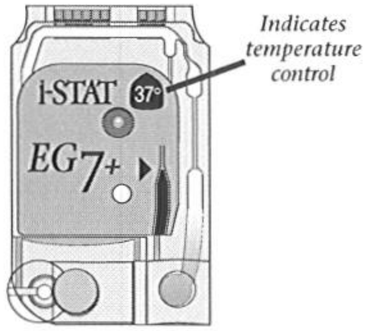
CARTRIDGE AND TEST INFORMATION

i-STAT sensors are available in a variety of panel configurations. Sensors are contained in cartridges with microfluidic components and, in some cartridges, calibration solution. i-STAT cartridges are used with the i-STAT Portable Clinical Analyzer or the Agilent Technologies Blood Analysis Module for the simultaneous quantitative determination of specific analytes and coagulation parameters in whole blood. Cartridges containing tests which require thermal control at 37°C can be used only with Analyzers which have the thermal control feature. A 37° symbol is printed on the analyzer case to indicate this capability.

CARTRIDGES SPECIFICATIONS

Example of cartridge that requires thermal control



Shelf Life: Refrigerated at 2 to 8°C (35 to 46°F) until expiration date
Room temperature at 18 to 30°C (64 to 86°F) for two weeks

Preparation for Use: Individual cartridges may be used after standing five minutes at room temperature. An entire box of cartridges should stand at room temperature for one hour.

All cartridges should be used immediately after opening pouch.

Sample Type: Fresh whole blood from arterial, venous, or skin punctures *(Note: Skin puncture is NOT a recommended sample type for ACT testing.)*

Sample Volume: 40µL, 65µL, or 95µL depending on cartridge type

Collection Options:
Test Timing:

Cartridges	Collection Devices		
	Syringes	Evacuated Tubes	Capillary Tubes
Cartridges which measure ionized calcium	• Without anticoagulant • With balanced heparin anticoagulant (syringe must be filled to indicated/ labeled capacity)	• Without anticoagulant • With sodium or lithium heparin anticoagulant (tubes must be filled to capacity)	• Without anticoagulant • With balanced heparin anticoagulant
Cartridges which perform ACT	• Without anticoagulant ONLY • Syringes must be plastic	• Without anticoagulant, clot activators, or serum separators ONLY • Devices used to transfer sample to cartridge must be plastic	• Not a recommended collection device for ACT
All other cartridges	• Without anticoagulant • With lithium, sodium, or balanced heparin anticoagulant	• Without anticoagulant • With lithium or sodium heparin anticoagulant	• Without anticoagulant • With balanced heparin anticoagulant • With sodium or lithium heparin if labeled for the measurement of electrolytes

Within 3 minutes after collection

- non-ACT cartridges when using capillary tubes, evacuated tubes or syringes without anticoagulant
- cartridges which measure lactate

Within 10 minutes after collection

- non-ACT cartridges when using evacuated tubes or syringes with anticoagulant

Notes: ***Anaerobic conditions must be maintained when analyzing pH, PO_2, PCO_2 or iCa.***
Evacuated tubes and syringes must be re-mixed before testing.

Analysis Time: ACT cartridge: to detection of endpoint, up to 1000 seconds
Other cartridges: 120 – 160 seconds

EXPECTED VALUES

Measured:

Test	Units	Reportable Range	Reference Range (arterial)	Reference Range (venous)
Sodium/Na	mmol/L (mEq/L)	100 – 180	138 – 146	138 – 146
Potassium/K	mmol/L (mEq/L)	2.0 – 9.0	3.5 – 4.9	3.5 – 4.9
Chloride/Cl	mmol/L (mEq/L)	65 – 140	98 – 109	98 – 109
Glucose/Glu	mmol/L	1.1 – 38.9	3.9 – 5.8	3.9 – 5.8
	mg/dL	20 – 700	70 – 105	70 – 105
Lactate/Lac	mmol/L	0.30 – 20.00	0.36 – 1.25	0.90 – 1.70
	mg/dL	2.7 – 180.2	3.2 – 11.3	8.1 – 15.3
Creatinine/Crea	mg/dL	0.2 – 20.0	0.6 – 1.3	0.6 – 1.3
	µmol/L	18 – 1768	53 – 115	53 – 115
pH		6.5 – 8.0	7.35 – 7.45	7.31 – 7.41
$P\text{CO}_2$	mmHg	5 – 130	35 – 45	41 – 51
	kPa	0.67 – 17.33	4.67 – 6.00	5.47 – 6.80
$P\text{O}_2$	mmHg	5 – 800	80 – 105	
	kPa	0.7 – 106.6	10.7 – 14.0	
Ionized Calcium/*i*Ca	mmol/L	0.25 – 2.50	1.12 – 1.32	1.12 – 1.32
	mg/dL	1.0 – 10.0	4.5 – 5.3	4.5 – 5.3
Urea Nitrogen/BUN	mg/dL	3 – 140	8 – 26	8 – 26
Urea	mmol/L	1 – 50	2.9 – 9.4	2.9 – 9.4
	mg/dL	6 – 300	17 – 56	17 – 56
Hematocrit/Hct	%PCV	10 – 75	38 – 51	38 – 51
	Fraction	0.10 – 0.75	0.38 – 0.51	0.38 – 0.51
Celite Activated Clotting Time / $^{\text{Celite}}$ACT	seconds	50 – 1000	74 – 125	74 – 125

Calculated:

Test	Units	Reportable Range	Reference Range (arterial)	Reference Range (venous)
Hemoglobin/Hb	g/dL	3 – 26	12 – 17	12 – 17
	g/L	34 – 255	120 – 170	120 – 170
	mmol/L	2 – 16	7 – 11	7 – 11
TCO_2	mmol/L (mEq/L)	1 – 85	23 – 27	24 – 29
HCO_3	mmol/L (mEq/L)	1 – 85	22 – 26	23 – 28
BE_{ecf}	mmol/L (mEq/L)	(-30) – (+30)	(-2) – (+3)	(-2) – (+3)
Anion Gap	mmol/L (mEq/L)	(-10) – (+99)	10 – 20	10 – 20
$s\text{O}_2$	%	n/a	95 – 98	

Reference: For additional information on the performance characteristics of specific assays, refer to the test informationpages in this section.

CARTRIDGE CONFIGURATIONS

i-STAT $^{EC}8^{+}$

Sodium (Na)
Potassium (K)
Chloride (Cl)
pH
PCO_2
Urea Nitrogen (BUN)/Urea
Glucose (Glu)
Hematocrit (Hct)
TCO_2^*
HCO_3^*
BE_{ecf}^*
Anion Gap* (Agap)
Hemoglobin* (Hb)

i-STAT 6^{+}

Sodium (Na)
Potassium (K)
Chloride (Cl)
Urea Nitrogen (BUN)/Urea
Glucose (Glu)
Hematocrit (Hct)
Hemoglobin* (Hb)

i-STAT $^{EC}6^{+}$

Sodium (Na)
Potassium (K)
Ionized Calcium (iCa)
pH
Glucose (Glu)
Hematocrit (Hct)
Hemoglobin* (Hb)

i-STAT $^{EC}4^{+}$

Sodium (Na)
Potassium (K)
Glucose (Glu)
Hematocrit (Hct)
Hemoglobin* (Hb)

i-STAT $^{E}3^{+}$

Sodium (Na)
Potassium (K)
Hematocrit (Hct)
Hemoglobin* (Hb)

i-STAT *G*

Glucose (Glu)

i-STAT *Crea*

Creatinine (Crea)

i-STAT $^{EG}7^{+}$

Sodium (Na)
Potassium (K)
Ionized Calcium (iCa)
Hematocrit (Hct)
pH
PCO_2
PO_2
TCO_2^*
HCO_3^*
BE_{ecf}^*
sO_2^*
Hemoglobin* (Hb)

i-STAT $^{EG}6^{+}$

Sodium (Na)
Potassium (K)
Hematocrit (Hct)TCO_2^*
pH
PCO_2
PO_2
HCO_3^*
BE_{ecf}^*
sO_2^*
Hemoglobin* (Hb)

i-STAT $^{G}3^{+}$

pH
PCO_2
PO_2
TCO_2^*
HCO_3^*
BE_{ecf}^*
sO_2^*

i-STAT $^{CG}4^{+}$

pH
PCO_2
PO_2
Lactate
TCO_2^*
HCO_3^*
BE_{ecf}^*
sO_2^*

i-STAT $^{CG}8^{+}$

Sodium (Na)
Potassium (K)
Ionized Calcium (iCa)
Glucose (Glu)
Hematocrit (Hct)
pH
PCO_2
PO_2
TCO_2^*
HCO_3^*
BE_{ecf}^*
sO_2^*
Hemoglobin* (Hb)

i-STAT $^{\text{Celite}}$ACT

Celite® ACT

** Calculated*

Celite is a registered trademark of Celite Corporation, Santa Barbara, CA, for its diatomaceous earth products.

SODIUM/NA

Sodium is measured by ion-selective electrode potentiometry. In the calculation of results for sodium, concentration is related to potential through the Nernst equation. The performance characteristics of the sensors are equivalent in all cartridge configurations.

The i-STAT System uses direct (undiluted) electrochemical methods. Values obtained by direct methods may differ from those obtained by indirect (diluted) methods.[1]

See below for information on factors affecting results. Certain substances, such as drugs, may affect analyte levels *in vivo*.[2]

If results appear inconsistent with the clinical assessment, the patient sample should be retested using another cartridge.

Intended Use

The test for sodium, as part of the i-STAT System, is intended for use in the *in vitro* quantification of arterial, venous, or capillary whole blood.

Contents

Each i-STAT cartridge contains one reference electrode (when potentiometric sensors are included in the cartridge configuration), sensors for measurement of specific analytes and a buffered aqueous calibrant solution of known concentrations. For cartridges that contain a sensor for the measurement of sodium, the calibrant solution contains 140mmol/L of sodium.

Expected Values

Test/Abbreviation	Units	Reportable Range	Reference Range[3]
Sodium/Na	mmol/L(mEq/L)	100–180	138 – 146

i-STAT measurements are performed on whole blood specimens. The i-STAT System has been calibrated to agree with standard laboratory and reference methods typically performed on serum or plasma. Therefore, the reference ranges presented above are equivalent to reference ranges derived from serum or plasma measurements with standard laboratory methods.

The reference range programmed into the analyzer and shown above is intended to be used as a guide for the interpretation of results. Since reference ranges may vary with demographic factors such as age, gender and heritage, it is recommended that reference ranges be determined for the population being tested.

Clinical Significance

Tests for sodium in the blood are important in the diagnosis and treatment of patients suffering from hypertension, renal failure or impairment, cardiac distress, disorientation, dehydration, nausea and diarrhea. Some causes of increased values for sodium include dehydration, diabetes insipidus, salt poisoning, skin losses, hyperaldosteronism and CNS disorders. Some causes for decreased values for sodium include dilutional hyponatremia (cirrhosis), depletional hyponatremia and syndrome of inappropriate ADH.

Performance Characteristics

The typical performance data summarized below was collected in health care facilities by health care professionals trained in the use of the i-STAT System and comparative methods.

Precision data was collected in multiple sites using the Performance Verification Guideline found in the i-STAT Implementation Guide. Similar results can be expected in future performance studies provided the same experimental design and data analysis procedures are followed. Method comparison data was collected using NCCLS guideline EP5[4]. Venous blood samples were collected in lithium heparin Vacutainer® tubes and analyzed in duplicate on the i-STAT System. A portion of the specimen was centrifuged and the separated plasma was analyzed in duplicate on comparative methods within 20 minutes of collection.

Deming regression analysis[5] was performed on the first replicate of each sample. In the method comparison table, n is the number of specimens in the data set, Sxx and Syy refer to estimates of imprecision based on the duplicates of the comparative and the i-STAT methods respectively, Sy.x is the standard error of the estimate, and r is the correlation coefficient.*

Method comparisons will vary from site to site due to differences in sample handling, comparative method calibration and other site specific variables.

Interference studies were based on NCCLS guideline EP7.[6]

* The usual warning relating to the use of regression analysis is summarized here as a reminder: For any analyte, "if the data is collected over a narrow range, the estimate of the regression parameters are relatively imprecise and may be biased. Therefore, predictions made from these estimates may be invalid".[4] The correlation coefficient, r, can be used as a guide to assess the adequacy of the comparative method range in overcoming this problem. As a guide, the range of data can be considered adequate if r>0.975.

Factors Affecting Results

Sodium heparin may increase sodium results up to 1mmol/L.

Interferent	**Effect**
β-hydroxybutyrate	16mmol/L (166mg/dL) β-hydroxybutyrate will decrease sodium results by 4mmol/L.

Precision Data (mmol/L(mEq/L))

Aqueous Control	Mean	SD	%CV
Level 1	113.5	0.61	0.5
Level 3	141.7	0.71	0.5

Method Comparison (mmol/L(mEq/L))

	Beckman Synchron CX®3	Kodak Ektachem™ 700	Nova STAT Profile® 5
n	189	142	192
Sxx	0.74	0.52	0.54
Syy	0.53	0.58	0.53
Slope	1.00	0.98	0.95
Int't	-0.11	3.57	5.26
Sy.x	1.17	1.04	1.53
Xmin	126	120	124
Xmax	148	148	148
r	0.865	0.937	0.838

Cartridge Comparison

The performance characteristics of the sensors are equivalent in all cartridge configurations. System difference analysis was performed on 40 patient samples using the i-STAT 6+ and i-STAT EC4+ cartridges. In the 130–150 mmol/L range the average difference was 0.750.

References

1. N.W. Tietz, E.L. Pruden, O. Siggaard-Andersen, "Electrolytes " in *Tietz Textbook of Clinical Chemistry—Second Edition,* C.A. Burtis and E.R. Ashwood, eds. (Philadelphia: W.B. Saunders Company, 1994).

2. D.S. Young, *Effects of Drugs on Clinical Laboratory Tests,* 3rd ed. (Washington, DC: American Association of Clinical Chemistry, 1990).

3. B.E. Statland, *Clinical Decision Levels for Lab Tests* (Oradell, NJ: Medical Economic Books, 1987).

4. National Committee for Clinical Laboratory Standards, *User Comparison of Quantitative Clinical Laboratory Methods Using Patient Sample; Proposed Guideline* (Villanova, PA: NCCLS, 1986).

5. P.J. Cornbleet and N. Gochman, "Incorrect Least-Squares Regression Coefficients in Method-Comparison Analysis," *Clinical Chemistry* 25:3, 432 (1979).

6. National Committee for Clinical Laboratory Standards, *Interference Testing in Clinical Chemistry; Proposed Guideline* (Villanova, PA: NCCLS, 1986).

POTASSIUM/K

Potassium is measured by ion-selective electrode potentiometry. In the calculation of results for potassium, concentration is related to potential through the Nernst equation. The performance characteristics of the sensors are equivalent in all cartridge configurations.

The i-STAT System uses direct (undiluted) electrochemical methods. Values obtained by direct methods may differ from those obtained by indirect (diluted) methods.[1]

See below for information on factors affecting results. Certain substances, such as drugs, may affect analyte levels *in vivo*.[2]

If results appear inconsistent with the clinical assessment, the patient sample should be retested using another cartridge.

Intended Use

The test for potassium, as part of the i-STAT System, is intended for use in the *in vitro* quantification of arterial, venous, or capillary whole blood.

Contents

Each i-STAT cartridge contains one reference electrode (when potentiometric sensors are included in the cartridge configuration), sensors for measurement of specific analytes and a buffered aqueous calibrant solution of known concentrations. For cartridges that contain a sensor for the measurement of potassium, the calibrant solution contains 4mmol/L of potassium.

Expected Values

Test/Abbreviation	Units	Reportable Range	Reference Range[3]
Potassium/K	mmol/L(mEq/L)	2 – 9	3.5 – 4.9*

* The reference range for potassium listed above has been reduced by 0.2mmol/L from the range cited in Reference 3 to account for the difference between serum and plasma results.

i-STAT measurements are performed on whole blood specimens. The i-STAT System has been calibrated to agree with standard laboratory and reference methods typically performed on serum or plasma. Therefore, the reference ranges presented above are equivalent to reference ranges derived from serum or plasma measurements with standard laboratory methods.

The reference range programmed into the analyzer and shown above is intended to be used as a guide for the interpretation of results. Since reference ranges may vary with demographic factors such as age, gender and heritage, it is recommended that reference ranges be determined for the population being tested.

Clinical Significance

Tests for potassium in the blood are important in the diagnosis and treatment of patients suffering from hypertension, renal failure or impairment, cardiac distress, disorientation, dehydration, nausea and diarrhea. Some causes of increased values for potassium include renal glomerular disease, adrenocortical insufficiency, diabetic ketacidosis (DKA), sepsis and in vitro hemolysis. Some causes of decreased values for potassium include renal tubular disease, hyperaldosteronism, treatment of DKA, hyperinsulinism, metabolic alkalosis and diuretic therapy.

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Performance Characteristics

The typical performance data summarized below was collected in health care facilities by health care professionals trained in the use of the i-STAT System and comparative methods.

Precision data was collected in multiple sites using the Performance Verification Guideline found in the i-STAT Implementation Guide. Similar results can be expected in future performance studies provided the same experimental design and data analysis procedures are followed. Method comparison data was collected using NCCLS guideline EP5[4]. Venous blood samples were collected in lithium heparin Vacutainer® tubes and analyzed in duplicate on the i-STAT System. A portion of the specimen was centrifuged and the separated plasma was analyzed in duplicate on comparative methods within 20 minutes of collection.

Deming regression analysis[5] was performed on the first replicate of each sample. In the method comparison table, n is the number of specimens in the data set, Sxx and Syy refer to estimates of imprecision based on the duplicates of the comparative and the i-STAT methods respectively, Sy.x is the standard error of the estimate, and r is the correlation coefficient.*

Method comparisons will vary from site to site due to differences in sample handling, comparative method calibration and other site specific variables.

Interference studies were based on NCCLS guideline EP7.[6]

* The usual warning relating to the use of regression analysis is summarized here as a reminder: For any analyte, "if the data is collected over a narrow range, the estimate of the regression parameters are relatively imprecise and may be biased. Therefore, predictions made from these estimates may be invalid".[4] The correlation coefficient, r, can be used as a guide to assess the adequacy of the comparative method range in overcoming this problem. As a guide, the range of data can be considered adequate if r>0.975.

Factors Affecting Results

If heparinized whole blood is allowed to stand before testing, potassium values will first decrease slightly, then increase over time. Potassium values will increase in iced specimens.

Potassium values from anticoagulated samples are preferred to serum values because 0.1 to 0.7 mmol/L potassium can be released from platelets[1] and red blood cells during the clotting process. Potassium values obtained from skin puncture samples may vary due to hemolysis or an increase in tissue fluid from improper technique during the collection procedure.

Precision Data (mmol/L(mEq/L))

Aqueous Control	Mean	SD	%CV
Level 1	5.61	0.064	1.14
Level 3	2.76	0.047	1.70

Method Comparison (mmol/L(mEq/L))

	Beckman Synchron CX®3	Kodak Ektachem™ 700	Nova STAT Profile® 5
n	.189	.142	.192
Sxx	0.060	0.031	0.065
Syy	0.055	0.059	0.055
Slope	0.97	1.06	0.99
Int't	0.02	-0.15	-0.01
Sy.x	0.076	0.060	0.112
Xmin	2.8	3.0	2.8
Xmax	5.7	9.2	5.8
r	0.978	0.993	0.948

Cartridge Comparison

The performance characteristics of the sensors are equivalent in all cartridge configurations. System difference analysis was performed on 40 patient samples using the i-STAT 6+ and i-STAT EC4+ cartridges. In the 3.0–5.0 mmol/L range the average difference was 0.049.

References

1. N.W. Tietz, E.L. Pruden, O. Siggaard-Andersen, "Electrolytes " in *Tietz Textbook of Clinical Chemistry—Second Edition,* C.A. Burtis and E.R. Ashwood, eds. (Philadelphia: W.B. Saunders Company, 1994).

2. D.S. Young, *Effects of Drugs on Clinical Laboratory Tests,* 3rd ed. (Washington, DC: American Association of Clinical Chemistry, 1990).

3. B.E. Statland, *Clinical Decision Levels for Lab Tests* (Oradell, NJ: Medical Economic Books, 1987).

4. National Committee for Clinical Laboratory Standards, *User Comparison of Quantitative Clinical Laboratory Methods Using Patient Sample; Proposed Guideline* (Villanova, PA: NCCLS, 1986).

5. P.J. Cornbleet and N. Gochman, "Incorrect Least-Squares Regression Coefficients in Method-Comparison Analysis," *Clinical Chemistry* 25:3, 432 (1979).

6. National Committee for Clinical Laboratory Standards, *Interference Testing in Clinical Chemistry; Proposed Guideline* (Villanova, PA: NCCLS, 1986).

CHLORIDE/CL

Chloride is measured by ion-selective electrode potentiometry. In the calculation of results for chloride, concentration is related to potential through the Nernst equation. The performance characteristics of the sensors are equivalent in all cartridge configurations.

The i-STAT System uses direct (undiluted) electrochemical methods. Values obtained by direct methods may differ from those obtained by indirect (diluted) methods.[1]

See below for information on factors affecting results. Certain substances, such as drugs, may affect analyte levels *in vivo*.[2] If results appear inconsistent with the clinical assessment, the patient sample should be retested using another cartridge.

Intended Use

The test for chloride, as part of the i-STAT System, is intended for use in the *in vitro* quantification of arterial, venous, or capillary whole blood.

Contents

Each i-STAT cartridge contains one reference electrode (when potentiometric sensors are included in the cartridge configuration), sensors for measurement of specific analytes and a buffered aqueous calibrant solution of known concentrations. For cartridges that contain a sensor for the measurement of chloride, the calibrant solution contains 100mmol/L of chloride.

Expected Values

Test/Abbreviation	Units	Reportable Range	Reference Range[3]
Chloride/CL	mmol/L(mEq/L)	65 – 140	98 – 109

i-STAT measurements are performed on whole blood specimens. The i-STAT System has been calibrated to agree with standard laboratory and reference methods typically performed on serum or plasma. Therefore, the reference ranges presented above are equivalent to reference ranges derived from serum or plasma measurements with standard laboratory methods.

The reference range programmed into the analyzer and shown above is intended to be used as a guide for the interpretation of results. Since reference ranges may vary with demographic factors such as age, gender and heritage, it is recommended that reference ranges be determined for the population being tested.

Clinical Significance

Tests for chloride in the blood are important in the diagnosis and treatment of patients suffering from hypertension, renal failure or impairment, cardiac distress, disorientation, dehydration, nausea and diarrhea. Some causes of increased values for chloride include prolonged diarrhea, renal tubular disease, hyperparathyroidism and dehydration. Some causes for decreased values for chloride include prolonged vomiting, burns, salt-losing renal disease, overhydration and thiazide therapy.

Performance Characteristics

The typical performance data summarized below was collected in health care facilities by health care professionals trained in the use of the i-STAT System and comparative methods.

Precision data was collected in multiple sites using the Performance Verification Guideline found in the i-STAT Implementation Guide. Similar results can be expected in future performance studies provided the same experimental design and data analysis procedures are followed. Method comparison data was collected using NCCLS guideline EP5[4]. Venous blood samples were collected in lithium heparin Vacutainer® tubes and analyzed in duplicate on the i-STAT System. A portion of the specimen was centrifuged and the separated plasma was analyzed in duplicate on comparative methods within 20 minutes of collection.

Deming regression analysis[5] was performed on the first replicate of each sample. In the method comparison table, n is the number of specimens in the data set, Sxx and Syy refer to estimates of imprecision based on the duplicates of the comparative and the i-STAT methods respectively, Sy.x is the standard error of the estimate, and r is the correlation coefficient.*

Method comparisons will vary from site to site due to differences in sample handling, comparative method calibration and other site specific variables.

Interference studies were based on NCCLS guideline EP7.[6]

* The usual warning relating to the use of regression analysis is summarized here as a reminder: For any analyte, "if the data is collected over a narrow range, the estimate of the regression parameters are relatively imprecise and may be biased. Therefore, predictions made from these estimates may be invalid".[4] The correlation coefficient, r, can be used as a guide to assess the adequacy of the comparative method range in overcoming this problem. As a guide, the range of data can be considered adequate if $r>0.975$.

Factors Affecting Results

Interferent	Effect
Salicylate	4mmol/L salicylate will increase chloride results by 3mmol/L.
Bromide	12.5mmol/L (100mg/dL) bromide will increase chloride results by 30mmol/L.
Lactate	11mmol/L (100mg/dL) lactate will increase chloride results by 3.5mmol/L.
β-hydroxybutyrate	16mmol/L (166mg/dL) β-hydroxybutyrate will increase chloride results by 6mmol/L.

Precision Data (mmol/L(mEq/L))

Aqueous Control	Mean	SD	%CV
Level 1	78.7	0.76	1.0
Level 3	105.8	0.80	0.8

Method Comparison (mmol/L(mEq/L))

	Beckman Synchron CX®3	Kodak Ektachem™ 700	Nova STAT Profile® 5
n	1.89	1.42	1.92
Sxx	1.27	0.41	0.89
Syy	0.88	0.90	0.88
Slope	0.99	0.88	0.93
Int't	-0.82	14.6	4.3
Sy.x	1.65	1.84	2.33
Xmin	.93	.63	.96
Xmax	1.14	1.28	1.17
r	0.817	0.914	0.752

References

1. N.W. Tietz, E.L. Pruden, O. Siggaard-Andersen, "Electrolytes " in *Tietz Textbook of Clinical Chemistry—Second Edition,* C.A. Burtis and E.R. Ashwood, eds. (Philadelphia: W.B. Saunders Company, 1994).

2. D.S. Young, *Effects of Drugs on Clinical Laboratory Tests,* 3rd ed. (Washington, DC: American Association of Clinical Chemistry, 1990).

3. B.E. Statland, *Clinical Decision Levels for Lab Tests* (Oradell, NJ: Medical Economic Books, 1987).

4. National Committee for Clinical Laboratory Standards, *User Comparison of Quantitative Clinical Laboratory Methods Using Patient Sample; Proposed Guideline* (Villanova, PA: NCCLS, 1986).

5. P.J. Cornbleet and N. Gochman, "Incorrect Least-Squares Regression Coefficients in Method-Comparison Analysis," *Clinical Chemistry* 25:3, 432 (1979).

6. National Committee for Clinical Laboratory Standards, *Interference Testing in Clinical Chemistry; Proposed Guideline* (Villanova, PA: NCCLS, 1986).

UREA NITROGEN/BUN

Urea is hydrolyzed to ammonium ions in a reaction catalyzed by the enzyme urease.

$$\text{Urea} + H_2O + 2H+ \xrightarrow{\text{urease}} 2NH^+_4 + CO_2$$

The ammonium ions are measured by an ion-selective electrode. In the calculation of results for urea, concentration is related to potential through the Nernst Equation. The performance characteristics of the sensors are equivalent in all cartridge configurations.

See below for information on factors affecting results. Certain substances, such as drugs, may affect analyte levels *in vivo*.[1]

If results appear inconsistent with the clinical assessment, the patient sample should be retested using another cartridge.

Intended Use

The test for urea nitrogen, as part of the i-STAT System, is intended for use in the *in vitro* quantification of arterial, venous, or capillary whole blood.

Contents

Each i-STAT cartridge contains one reference electrode (when potentiometric sensors are included in the cartridge configuration), sensors for measurement of specific analytes and a buffered aqueous calibrant solution of known concentrations. For cartridges that contain a sensor for the measurement of urea nitrogen, the calibrant solution contains 11.2mg/dL of urea nitrogen.

Expected Values

Test/Abbreviation	Units	Reportable Range	Reference Range[2]
Urea Nitrogen/BUN	mg/dL	3 – 140	8 – 26

To convert a BUN result from mg/dL to mmol/urea, multiply the displayed BUN result by 0.357.

i-STAT measurements are performed on whole blood specimens. The i-STAT System has been calibrated to agree with standard laboratory and reference methods typically performed on serum or plasma. Therefore, the reference ranges presented above are equivalent to reference ranges derived from serum or plasma measurements with standard laboratory methods.

The reference range programmed into the analyzer and shown above is intended to be used as a guide for the interpretation of results. Since reference ranges may vary with demographic factors such as age, gender and heritage, it is recommended that reference ranges be determined for the population being tested.

Clinical Significance

An abnormally high level of urea nitrogen in the blood is an indication of kidney function impairment or failure. Some other causes of increased values for urea nitrogen include prerenal azotemia (e.g. shock), postrenal azotemia, GI bleeding and a high protein diet. Some causes of decreased values for urea nitrogen include pregnancy, severe liver insufficiency, overhydration and malnutrition.

Performance Characteristics

The typical performance data summarized below was collected in health care facilities by health care professionals trained in the use of the i-STAT System and comparative methods.

Precision data was collected in multiple sites using the Performance Verification Guideline found in the i-STAT Implementation Guide. Similar results can be expected in future performance studies provided the same experimental design and data analysis procedures are followed. Method comparison data was collected using NCCLS guideline EP5[3]. Venous blood samples were collected in lithium heparin Vacutainer® tubes and analyzed in duplicate on the i-STAT System. A portion of the specimen was centrifuged and the separated plasma was analyzed in duplicate on comparative methods within 20 minutes of collection.

Deming regression analysis[4] was performed on the first replicate of each sample. In the method comparison table, n is the number of specimens in the data set, Sxx and Syy refer to estimates of imprecision based on the duplicates of the comparative and the i-STAT methods respectively, Sy.x is the standard error of the estimate, and r is the correlation coefficient.*

Method comparisons will vary from site to site due to differences in sample handling, comparative method calibration and other site specific variables.

Interference studies were based on NCCLS guideline EP7.[5]

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* The usual warning relating to the use of regression analysis is summarized here as a reminder: For any analyte, "if the data is collected over a narrow range, the estimate of the regression parameters are relatively imprecise and may be biased. Therefore, predictions made from these estimates may be invalid".[3] The correlation coefficient, r, can be used as a guide to assess the adequacy of the comparative method range in overcoming this problem. As a guide, the range of data can be considered adequate if r>0.975.

Factors Affecting Results

Endogenous ammonium ions will not affect results.

Precision Data (mg/dL)

Aqueous Control	Mean	SD	%CV
Level 1	4.3	0.40	9.4
Level 3	66.5	2.16	3.2

Method Comparison (mg/dL)

	Beckman Synchron CX®3	Kodak Ektachem™ 700
n	1.89	1.42
Sxx	0.57	0.46
Syy	0.96	0.86
Slope	0.98	0.98
Int't	0.10	-0.28
Sy.x	1.47	1.73
Xmin	3.0	3.0
Xmax	1.15	1.38
r	0.9970.996	

Cartridge Comparison

The performance characteristics of the sensors are equivalent in all cartridge configurations. System difference analysis was performed on 40 patient samples using the i-STAT 6+ and i-STAT D4+ cartridges. In the 25–60 mg/dL range the average difference was -1.13. In the 60–140 mg/dL range the average difference was -0.77.

References

1. D.S. Young, *Effects of Drugs on Clinical Laboratory Tests,* 3rd ed. (Washington, DC: American Association of Clinical Chemistry, 1990).

2. B.E. Statland, *Clinical Decision Levels for Lab Tests* (Oradell, NJ: Medical Economic Books, 1987).

3. National Committee for Clinical Laboratory Standards, *User Comparison of Quantitative Clinical Laboratory Methods Using Patient Sample; Proposed Guideline* (Villanova, PA: NCCLS, 1986).

4. P.J. Cornbleet and N. Gochman, "Incorrect Least-Squares Regression Coefficients in Method-Comparison Analysis," *Clinical Chemistry* 25:3, 432 (1979).

5. National Committee for Clinical Laboratory Standards, *Interference Testing in Clinical Chemistry; Proposed Guideline* (Villanova, PA: NCCLS, 1986).

GLUCOSE/GLU

Glucose is measured amperometrically. Oxidation of glucose, catalyzed by the enzyme glucose oxidase, produces hydrogen peroxide (H_2O_2). The liberated hydrogen peroxide is oxidized at the electrode to produce a current which is proportional to the sample glucose concentration. The performance characteristics of the sensors are equivalent in all cartridge configurations.

$$\beta\text{-D-glucose} + H_2O + O_2 \xrightarrow{\textit{glucose oxidase}} \text{D-gluconic acid} + H_2O_2$$

$$H_2O_2 \longrightarrow 2H^+ + O_2 + 2e^-$$

See below for information on factors affecting results. Certain substances, such as drugs, may affect analyte levels *in vivo*.[1] If results appear inconsistent with the clinical assessment, the patient sample should be retested using another cartridge.

Intended Use

The test for glucose, as part of the i-STAT System, is intended for use in the *in vitro* quantification of arterial, venous, or capillary whole blood.

Contents

Each i-STAT cartridge contains one reference electrode (when potentiometric sensors are included in the cartridge configuration), sensors for measurement of specific analytes and a buffered aqueous calibrant solution of known concentrations. For cartridges that contain a sensor for the measurement of glucose, the calibrant solution contains 90 mg/dL of glucose.

Expected Values

Test/Abbreviation	Units	Reportable Range	Reference Range[2]
Glucose/Glu	mg/dL	20 – 700	70 – 105
(fasting)	mmol/L	1.1 – 38.9	3.9 – 5.8

To convert a glucose result from mg/dL to mmol/L, multiply the displayed glucose result by 0.055.

i-STAT measurements are performed on whole blood specimens. The i-STAT System has been calibrated to agree with standard laboratory and reference methods typically performed on serum or plasma. Therefore, the reference ranges presented above are equivalent to reference ranges derived from serum or plasma measurements with standard laboratory methods.

The reference range programmed into the analyzer and shown above is intended to be used as a guide for the interpretation of results. Since reference ranges may vary with demographic factors such as age, gender and heritage, it is recommended that reference ranges be determined for the population being tested.

Clinical Significance

Glucose is a primary energy source for the body and the only source of nutrients for brain tissue. Measurements for determination of blood glucose levels are important in the diagnosis and treatment of patients suffering from diabetes and hypoglycemia. Some causes for increased values of glucose include diabetes mellitus, pancreatitis, endocrine disorders (e.g. Cushing's syndrome), drugs (e.g. steroids, thyrotoxicosis), chronic renal failure, stress, or I.V. glucose infusion. Some causes of decreased values of glucose include insulinoma, adrenocortical insufficiency, hypopituitarism, massive liver disease, ethanol ingestion, reactive hypoglycemia, and glycogen storage disease.

Performance Characteristics

The typical performance data summarized below was collected in health care facilities by health care professionals trained in the use of the i-STAT System and comparative methods.

Precision data was collected in multiple sites using the Performance Verification Guideline found in the i-STAT Implementation Guide. Similar results can be expected in future performance studies provided the same experimental design and data analysis procedures are followed. Method comparison data was collected using NCCLS guideline EP5[3]. Venous blood samples were collected in lithium heparin Vacutainer® tubes and analyzed in duplicate on the i-STAT System. A portion of the specimen was centrifuged and the separated plasma was analyzed in duplicate on comparative methods within 20 minutes of collection.

Deming regression analysis[4] was performed on the first replicate of each sample. In the method comparison table, n is the number of specimens in the data set, Sxx and Syy refer to estimates of imprecision based on the duplicates of the comparative and the i-STAT methods respectively, Sy.x is the standard error of the estimate, and r is the correlation coefficient.*

Method comparisons will vary from site to site due to differences in sample handling, comparative method calibration and other site specific variables.

Interference studies were based on NCCLS guideline EP7.[5]

* The usual warning relating to the use of regression analysis is summarized here as a reminder: For any analyte, "if the data is collected over a narrow range, the estimate of the regression parameters are relatively imprecise and may be biased. Therefore, predictions made from these estimates may be invalid".[3] The correlation coefficient, r, can be used as a guide to assess the adequacy of the comparative method range in overcoming this problem. As a guide, the range of data can be considered adequate if r>0.975.

Factors Affecting Results*

Glucose values will decrease in whole blood samples over time. Venous blood glucose is as much as 7mg/dL less than capillary blood glucose as a result of tissue utilization.[6]

Interferent	Effect
Bromide	12.5mmol/L (100mg/dL) bromide will decrease glucose results by 30 mg/dL.
pH	Values below 7.4 at 37°C decrease results by approximately 0.9 mg/dL (0.05 mmol/L) per 0.1 pH units. Values above 7.4 at 37°C increase results by approximately 0.8 mg/dL (0.04 mmol/L) per 0.1 pH units.
Hydroxyurea (Droxia®, Hydrea®)	Hydroxyurea may cause significant errors in the measurement of glucose with the i-STAT System. Use an alternative method to measure glucose when patients have been administered hydroxyurea. See note (1) below for typical uses of this drug and note (2) below for details of the interference. Droxia and Hydrea are registered trademarks of Bristol-Meyers Squibb Company, Princeton, NJ.
PO_2	Oxygen levels of less than 20 mmHg (2.66 kPa) at 37°C may decrease results.

*It is possible that other interfering substance may be encountered. These results are representative and your results may differ somewhat due to test-to-test variation. The degree of interference at concentrations other than those listed might not be predictable.

Notes:

1) Hydroxyurea is a DNA synthesis inhibitor used in the treatment of various forms of cancer, sickle cell anemia, and HIV infection. This drug is used to treat malignancies including melanoma, metastatic ovarian cancer, and chronic myelogenous leukemia. It is also used in the treatment of polycythemia vera, thrombocytopenia, and psoriasis. At typical doses ranging from 500 mg to 2 g/day, concentrations of hydroxyurea in patients' blood may be sustained at approximately 100 to 500 µmol/L. Higher concentrations may be observed soon after dosing or at higher therapeutic doses.

2) For every 100 µmol/L hydroxyurea in the whole blood sample, glucose will be increased by approximately 8 mg/dL (0.44 mmol/L), up to a whole blood hydroxyurea concentration of at least 921 µmol/L (maximum concentration tested). The magnitude of the bias is independent of the glucose level over a range of at least 75 mg/dL (4.2 mmol/L) to 645 mg/dL (35.8 mmol/L).

Ascorbic acid up to 0.63mmol/L (11mg/dL), uric acid up to 12mg/dL, lactate up to 11mmol/L (100mg/dL), β-hydroxybutyrate up to 16mmol/L (166mg/dL), acetoacetate up to 10mmol/L (100mg/dL), acetaminophen up to 1.32mmol/L (20mg/dL) and hematocrit levels between 15–75 %PCV were tested and found not to interfere with glucose results.

Precision Data (mg/dL)

Aqueous Control	Mean	SD	%CV
Level 1	214.5	6.74	3.1
Level 3	55.3	1.43	2.6

Method Comparison (mg/dL)

	Beckman Synchron CX®3	Kodak Ektachem™ 700	Nova STAT Profile® 5
n	189	142	192
Sxx	3.52	0.93	2.88
Syy	7.79	6.65	7.79
Slope	1.07	1.05	1.16
Int't	-6.69	-5.53	-19.83
Sy.x	11.17	9.64	16.08
Xmin	60	52	65
Xmax	450	450	425
r	0.989	0.992	0.977

Cartridge Comparison

System difference analysis was performed on 40 patient samples using the i-STAT 6+ and i-STAT EC4+ cartridges. In the 100–200mg/dL range the average difference was 1.77. In the 200–300mg/dL range the average difference was 3.7.

References

1. D.S. Young, *Effects of Drugs on Clinical Laboratory Tests,* 3rd ed. (Washington, DC: American Association of Clinical Chemistry, 1990).

2. P.C. Painter, J.Y. Cope, J.L. Smith, "Reference Ranges, Table 41-20" in *Tietz Textbook of Clinical Chemistry—Second Edition,* C.A. Burtis and E.R. Ashwood, eds. (Philadelphia: W.B. Saunders Company, 1994).

3. NCCLS. *Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline.* NCCLS document EP9-A [ISBN 1-56238-283-7]. NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA 1995.

4. P.J. Cornbleet and N. Gochman, "Incorrect Least-Squares Regression Coefficients in Method-Comparison Analysis," *Clinical Chemistry* 25:3, 432 (1979).

5. NCCLS. *Interference Testing in Clinical Chemistry; Proposed Guideline.* NCCLS document EP7-P [ISBN 1-56238-020-6]. NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA 1986.

6. D.S. Young and E.W. Bermes, "Influence of Site Collection on Blood Gases and pH," in *Tietz Textbook of Clinical Chemistry—Second Edition,* C.A. Burtis and E.R. Ashwood, eds. (Philadelphia:

Droxia and Hydrea are registered trademarks of Bristol-Myers Squibb Company, Princeton, NJ.

HEMATOCRIT/HCT *and calculated Hemoglobin*

Hematocrit is determined conductometrically. The measured conductivity, after correction for electrolyte concentration, is inversely related to the hematocrit. The performance characteristics of the sensors are equivalent in all cartridge configurations.

See below for information on factors affecting results. Certain substances, such as drugs, may affect analyte levels *in vivo*.[1]

If results appear inconsistent with the clinical assessment, the patient sample should be retested using another cartridge.

Intended Use

The test for hematocrit, as part of the i-STAT System, is intended for use in the *in vitro* quantification of arterial, venous, or capillary whole blood.

Contents

Each i-STAT cartridge contains one reference electrode (when potentiometric sensors are included in the cartridge configuration), sensors for measurement of specific analytes and a buffered aqueous calibrant solution of known concentrations and known conductance.

Expected Values

Test/Abbreviation	Units	Reportable Range	Reference Range[2]
Hematocrit/Hct	%PCV	10 – 75	38 – 51*
	Fraction	0.10 – 0.75	0.38 – 0.51
Hemoglobin/Hb	g/dL	3 – 26	12 – 17
	g/L	34 – 255	120 – 170

* The reference ranges for hematocrit and hemoglobin span both female and male populations. Except for hematocrit values below 7% PCV, values outside the reportable ranges are flagged.

To convert a result from % PCV to fraction packed cell volume, divide the displayed hematocrit result by 100.

For the measurement of hematocrit, the i-STAT System has been calibrated to agree with methods using K_3EDTA as anticoagulant.

* While NaEDTA and K_2EDTA are recommended by NCCLS[3], K_3EDTA is currently the most popular anticoagulant despite the fact that mean cell volumes are decreased by approximately 4%.

The reference range programmed into the analyzer and shown above is intended to be used as a guide for the interpretation of results. Since reference ranges may vary with demographic factors such as age, gender and heritage, it is recommended that reference ranges be determined for the population being tested.

Clinical Significance

Hematocrit is a measurement of the volume of red blood cells. This is a key indicator of the body's state of hydration, anemia or severe blood loss, as well as the blood's ability to transport oxygen. Some causes of increased values of hematocrit include dehydration, burns, impaired ventilation and renal disorders. Some causes for decreased values of hematocrit include hemolytic anemias, iron deficiency, marrow depression or blood loss

Performance Characteristics

The typical performance data summarized below was collected in health care facilities by health care professionals trained in the use of the i-STAT System and comparative methods.

Precision data was collected in multiple sites using the Performance Verification Guideline found in the i-STAT Implementation Guide. Similar results can be expected in future performance studies provided the same experimental design and data analysis procedures are followed. Method comparison data was collected using NCCLS guideline EP5[4]. Venous blood samples, collected in lithium heparin Vacutainer® tubes, were analyzed in duplicate on the i-STAT System and on the comparative methods for hematocrit within 20 minutes of collection.

Deming regression analysis[5] was performed on the first replicate of each sample. In the method comparison table, n is the number of specimens in the data set, Sxx and Syy refer to estimates of imprecision based on the duplicates of the comparative and the i-STAT methods respectively, Sy.x is the standard error of the estimate, and r is the correlation coefficient.*

Method comparisons will vary from site to site due to differences in sample handling, comparative method calibration and other site specific variables.

Interference studies were based on NCCLS guideline EP7.[6]

* The usual warning relating to the use of regression analysis is summarized here as a reminder: For any analyte, "if the data is collected over a narrow range, the estimate of the regression parameters are relatively imprecise and may be biased. Therefore, predictions made from these estimates may be invalid".[5] The correlation coefficient, r, can be used as a guide to assess the adequacy of the comparative method range in overcoming this problem. As a guide, the range of data can be considered adequate if r>0.975.

Factors Affecting Results

Interferent	**Effect**
WBC	Grossly elevated white blood cell counts may increase results.
Total Protein	When the displayed hematocrit value is less than 40% PCV, the i-STAT result will be decreased/increased by 1% PCV for each decrease/increase of 1 g/dL in total protein outside the 6.5 to 8.0 g/dL range. When the hematocrit value is greater than 40% PCV, the i-STAT result will be decreased/increased by 0.75% PCV for each decrease/increase of 1 g/dL in total protein outside the 6.5 to 8.0 g/dL range.

Precision Data (%PCV)

Whole Blood Control	Mean	SD	%CV
Low	29.9	0.68	2.3
High	49.8	1.00	2.0

Method Comparison (%PCV)

	Coulter® S Plus	Technicon™ H-1	Nova STAT Profile® 5
n	142	182	192
Sxx	0.50	0.50	0.46
Syy	1.09	1.30	1.31
Slope	0.98	1.09	1.06
Int't	1.78	-3.02	-3.98
Sy.x	2.03	2.32	2.063
Xmin	.18	.21	.21
Xmax	.51	.50	.50
r	0.952	0.910	0.932

Cartridge Comparison

The performance characteristics of the sensors are equivalent in all cartridge configurations. System difference analysis was performed on 40 patient samples using the i-STAT 6+ and i-STAT E3+ cartridges. In the 15–30 %PCV range the average difference was 0.462. In the 30–50 %PCV range the average difference was 0.097.

Calculated Result for Hemoglobin

The i-STAT System provides a calculated hemoglobin result which is determined as follows[7]:

hemoglobin (g/dL) = hematocrit (decimal fraction) x 34

To convert a hemoglobin result from g/dL to mmol/L, multiply the displayed result by 0.621. The calculation of hemoglobin from hematocrit assumes a normal MCHC.

References

1. D.S. Young, *Effects of Drugs on Clinical Laboratory Tests,* 3rd ed. (Washington, DC: American Association of Clinical Chemistry, 1990).

2. B.E. Statland, *Clinical Decision Levels for Lab Tests* (Oradell, NJ: Medical Economic Books, 1987).

3. National Committee for Clinical Laboratory Standards, *Procedure for Determining Packed Cell Volume by the Microhematocrit Method - 2nd edition; Approved Standard* (Villanova, PA: NCCLS, 1992).

4. National Committee for Clinical Laboratory Standards, *User Comparison of Quantitative Clinical Laboratory Methods Using Patient Sample; Proposed Guideline* (Villanova, PA: NCCLS, 1986).

5. P.J. Cornbleet and N. Gochman, "Incorrect Least-Squares Regression Coefficients in Method-Comparison Analysis," *Clinical Chemistry* 25:3, 432 (1979).

6. National Committee for Clinical Laboratory Standards, *Interference Testing in Clinical Chemistry; Proposed Guideline* (Villanova, PA: NCCLS, 1986).

7. J.D. Bower, P.G. Ackerman and G. Toto, eds., "Evaluation of Formed Elements of Blood," in *Clinical Laboratory Methods* (St. Louis: The C.V. Mosby Company, 1974).

IONIZED CALCIUM/*i*Ca

Ionized calcium is measured by ion-selective electrode potentiometry. In the calculation of results for ionized calcium concentration is related to potential through the Nernst equation. Results are measured at 37ÞC using cartridges that require thermal control and are corrected to 37°C using cartridges that do not require thermal control. The performance characteristics of the sensors are equivalent in all cartridge configurations.

See below for information on factors affecting results. Certain substances, such as drugs, may affect analyte levels *in vivo*.[1]

If results appear inconsistent with the clinical assessment, the patient sample should be retested using another cartridge.

Intended Use

The test for ionized calcium, as part of the i-STAT System, is intended for use in the *in vitro* quantification of arterial, venous, or capillary whole blood.

Contents

Each i-STAT cartridge contains one reference electrode (when potentiometric sensors are included in the cartridge configuration), sensors for measurement of specific analytes and a buffered aqueous calibrant solution of known concentrations. For cartridges that contain a sensor for the measurement of ionized calcium, the calibrant solution contains 1.25mmol/L of ionized calcium.

Expected Values

Test/Abbreviation	Units	Reportable Range	Reference Range[2]
Ionized Calcium/iCa	mmol/L	0.25 – 2.50	1.12 – 1.32
	mg/dL	1.0 – 10.0	4.5 – 5.3

To convert a result from mmol/L to mg/dL, multiply the displayed result by 4.

For the measurement of ionized calcium, the i-STAT System has been calibrated to agree with standard direct electrochemical methods performed on whole blood.

The reference range programmed into the analyzer and shown above is intended to be used as a guide for the interpretation of results. Since reference ranges may vary with demographic factors such as age, gender and heritage, it is recommended that reference ranges be determined for the population being tested.

Clinical Significance

Although most of the calcium in blood is bound to protein or complexed to smaller anionic species, the biologically active fraction of calcium is free ionized calcium. Through its role in a number of enzymatic reactions and in membrane transport mechanisms, ionized calcium is vitally important in blood coagulation, nerve conduction, neuromuscular transmission and in muscle contraction. Increased ionized calcium (hypercalcemia) may result in coma. Other symptoms reflect neuromuscular disturbances, such as hyperreflexia and/or neurologic abnormalities such as neurasthenia, depression or psychosis. Decreased ionized calcium (hypocalcemia) often results in cramps (tetany), reduced cardiac stroke work and depressed left ventricular function. Prolonged hypocalcemia may result in bone demineralization (osteoporosis) which can lead to spontaneous fractures. Measurements of ionized calcium have proven of value under the following clinical conditions: transfusion of citrated blood, liver transplantation, open heart surgery, neonatal hypocalcemia, renal disease, hyperparathyroidism, malignancy, hypertension and pancreatitis.

Performance Characteristics

The typical performance data summarized below was collected in health care facilities by health care professionals trained in the use of the i-STAT System and comparative methods.

Precision data was collected in multiple sites using the Performance Verification Guideline found in the i-STAT Implementation Guide. Similar results can be expected in future performance studies provided the same experimental design and data analysis procedures are followed. Method comparison data was collected using NCCLS guideline EP5[3]. Venous blood samples were collected in lithium heparin Vacutainer® tubes and analyzed in duplicate on the i-STAT System and on the comparative methods within 10 minutes of each other.

Deming regression analysis[4] was performed on the first replicate of each sample. In the method comparison table, n is the number of specimens in the data set, Sxx and Syy refer to estimates of imprecision based on the duplicates of the comparative and the i-STAT methods respectively, Sy.x is the standard error of the estimate, and r is the correlation coefficient.*

Method comparisons will vary from site to site due to differences in sample handling, comparative method calibration and other site specific variables.

Interference studies were based on NCCLS guideline EP7.[5]

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* The usual warning relating to the use of regression analysis is summarized here as a reminder: For any analyte, "if the data is collected over a narrow range, the estimate of the regression parameters are relatively imprecise and may be biased. Therefore, predictions made from these estimates may be invalid".[3] The correlation coefficient, r, can be used as a guide to assess the adequacy of the comparative method range in overcoming this problem. As a guide, the range of data can be considered adequate if r>0.975.

Factors Affecting Results

Venous stasis (prolonged tourniquet application) and forearm exercise may increase ionized calcium due to a decrease in pH caused by localized production of lactic acid[6]. Exposing the sample to air will cause an increase in pH due to the loss of CO_2 which will decrease ionized calcium.

Heparin binds calcium. Each unit of heparin added per mL of blood will decrease ionized calcium by 0.01mmol/L.[6] Therefore, the correct ratio of heparin anticoagulant to blood must be achieved during sample collection. Intravenous injection of 10,000 units of heparin has been shown in adults to cause a significant decrease of ionized calcium of about 0.03mmol/L.[6]

Interferent	**Effect**
Magnesium	1.0 mmol/L magnesium above normal will increase ionized calcium results by 0.04mmol/L.

Precision Data (mmol/L)

Aqueous Control	Mean	SD	%CV
Level 1	1.56	0.018	1.14
Level 3	0.76	0.0121.56	

Method Comparison (mmol/L)

	Radiometer ICA1	Nova STAT Profile
n	.47	.57
Sxx	0.009	0.017
Syy	0.017	0.017
Slope	0.925	0.960
Int't	0.113	0.062
Sy.x	0.035	0.029
Xmin	0.46	0.53
Xmax	2.05	2.05
r	0.982	0.982

References

1. D.S. Young, *Effects of Drugs on Clinical Laboratory Tests,* 3rd ed. (Washington, DC: American Association of Clinical Chemistry, 1990).

2. P.C. Painter, J.Y. Cope, J.L. Smith, *"Reference Ranges, Table 41–20" in Tietz Textbook of Clinical Chemistry—Second Edition,* C.A. Burtis and E.R. Ashwood, eds. (Philadelphia: W.B. Saunders Company, 1994).

3. National Committee for Clinical Laboratory Standards, *User Comparison of Quantitative Clinical Laboratory Methods Using Patient Sample; Proposed Guideline* (Villanova, PA: NCCLS, 1986).

4. P.J. Cornbleet and N. Gochman, "Incorrect Least-Squares Regression Coefficients in Method-Comparison Analysis," *Clinical Chemistry* 25:3, 432 (1979).

5. National Committee for Clinical Laboratory Standards, *Interference Testing in Clinical Chemistry; Proposed Guideline* (Villanova, PA: NCCLS, 1986).

6. D. Fraser, G. Jones, S.W. Kooh, and I. Raddle, "Calcium and Phosphate Metabolism" in *Tietz Textbook of Clinical Chemistry—Second Edition,* C.A. Burtis and E.R. Ashwood, eds. (Philadelphia: W.B. Saunders Company, 1994).

PO_2 and *calculated values for Saturated Oxygen (sO_2)*

PO_2 is measured amperometrically. The oxygen sensor is similar to a conventional Clark electrode. Oxygen permeates through a gas permeable membrane from the blood sample into an internal electrolyte solution where it is reduced at the cathode. The oxygen reduction current is proportional to the dissolved oxygen concentration. The performance characteristics of the sensors are equivalent in all cartridge configurations.

See below for information on factors affecting results. Certain substances, such as drugs, may affect analyte levels *in vivo*.[1]

If results appear inconsistent with the clinical assessment, the patient sample should be retested using another cartridge.

Intended Use

The test for PO_2, as part of the i-STAT System, is intended for use in the *in vitro* quantification of arterial, venous, or capillary whole blood.

Contents

Each i-STAT cartridge configuration with sensors for the measurement of pH, PCO_2 and PO_2 contains heating elements, one reference electrode, sensors for measurement of specific analytes, and a buffered aqueous calibrant solution of known concentrations. For cartridges that contain sensors for the measurement of pH, PCO_2 and PO_2, the calibrant solution is buffered to pH 7.43, and contains 30 mmHg of PCO_2 and approximately 160 mmHg of PO_2 (which is equilibrated to the atmospheric PO_2 during the calibration cycle).

Expected Values

Test	Units	Reportable Range	Reference Range[2]
PO_2	mmHg	5 – 800	80 – 105
	kPa	0.7 – 106.6	10.7 – 14.0
sO_2*	%	not applicable	95 – 98

* Calculated

To convert PO_2 results from mmHg to kPa, multiply the displayed result by 0.133.

The i-STAT System has been calibrated to agree with standard blood gas methods for pH, PCO_2 and PO_2 performed on arterial whole blood. Therefore, the reference ranges listed above for the i-STAT measurements are equivalent to reference ranges published in the literature. The reference ranges shown are for a healthy population. Interpretation of blood gas measurements depend on the underlying condition (eg. patient temperature, ventilation, posture and circulatory status).

Clinical Significance

PO_2 (partial pressure of oxygen) is a measurement of the tension or pressure of oxygen dissolved in blood. Some causes for decreased values of PO_2 include decreased pulmonary ventilation (e.g. airway obstruction or trauma to the brain), impaired gas exchange between alveolar air and pulmonary capillary blood (e.g. bronchitis, emphysema, or pulmonary edema), and alteration in the flow of blood within the heart or lungs (e.g. congenital defects in the heart or shunting of venous blood into the arterial system without oxygenation in the lungs).

sO_2 (oxygen saturation) is the amount of oxyhemoglobin expressed as a fraction of the total amount of hemoglobin able to bind oxygen (oxyhemoglobin plus deoxyhemoglobin).

$$sO_2\,\% = \frac{C_{O_2Hb}}{C_{O_2}\,Hb + C_{HHb}} \; x\ 100$$

where O_2Hb is oxyhemoglobin and HHb is deoxyhemoglobin

sO_2 is calculated from measured PO_2, PCO_2 and pH. However, this calculation assumes normal affinity of oxygen for hemoglobin (it does not take into consideration extracellular erythrocyte diphosphoglycerate (2, 3 DPG) concentrations which affect the oxyhemoglobin dissociation curve) and assumes that normal amounts of disfunctional hemoglobin (carboxy-, met- and sulfhemoglobin) are present. Oxygen saturation is a useful predictor of the amount of oxygen that is available for tissue perfusion. Some causes for decreased values of sO_2 include low PO_2 or impaired ability of hemoglobin to carry oxygen.

Performance Characteristics

The typical performance data summarized below was collected in a health care facility by health care professionals trained in the use of the i-STAT System and comparative method.

Precision data was collected in multiple sites using the Performance Verification Guideline found in the i-STAT Implementation Guide. Similar results can be expected in future performance studies provided the same experimental design and data analysis procedures are followed. Method comparison data was collected using NCCLS guideline EP5[6]. Arterial blood samples were collected from hospital patients in 3cc blood gas syringes and were analyzed in duplicate on the i-STAT System and the Radiometer ABL500 within 5 minutes of each other.

Deming regression analysis[7] was performed on the first replicate of each sample. In the method comparison table, n is the number of specimens in the data set, Sxx and Syy refer to estimates of imprecision based on the duplicates of the comparative and the i-STAT methods respectively, Sy.x is the standard error of the estimate, and r is the correlation coefficient.* Method comparisons will vary from site to site due to differences in sample handling, comparative method calibration and other site specific variables.

* The usual warning relating to the use of regression analysis is summarized here as a reminder: For any analyte, "if the data is collected over a narrow range, the estimate of the regression parameters are relatively imprecise and may be biased. Therefore, predictions made from these estimates may be invalid".[6] The correlation coefficient, r, can be used as a guide to assess the adequacy of the comparative method range in overcoming this problem. As a guide, the range of data can be considered adequate if r>0.975.

Precision Data (mmHg)

Aqueous Control	Mean	SD	%CV
Level 1	65.1	3.12	4.79
Level 3	146.5	6.00	4.10

Method Comparison (mmHg)

	Radiometer ABL500
n	.45
Sxx	3.699
Syy	2.776
Slope	1.023
Int't	-2.560
Sy.x	2.517
r	0.996

Factors Affecting Results

Exposure of the sample to air will cause an increase in PO_2 when values are below 150 mmHg and a decrease in PO_2 when values are above 150 mmHg (approximate PO_2 of room air).

Standing anaerobically at room temperature will decrease pH at a rate of 0.03 per hour, will increase PCO_2 by approximately 4 mmHg per hour and will decrease PO_2 at a rate of 2–6 mmHg per hour.[3]

Factors Affecting Calculated Results

sO_2 values calculated from a measured PO_2 and an assumed oxyhemoglobin dissociation curve may differ significantly from the direct measurement.[8]

References

1. D.S. Young, *Effects of Drugs on Clinical Laboratory Tests,* 3rd ed. (Washington, DC: American Association of Clinical Chemistry, 1990).

2. B.E. Statland, *Clinical Decision Levels for Lab Tests* (Oradel, NJ: Medical Economic Books, 1987).

3. E.L. Pruden, O. Siggaard-Andersen, and N.W. Tietz, "Blood Gases and pH," in *Tietz Textbook of Clinical Chemistry—Second Edition,* C.A. Burtis and E.R. Ashwood, eds. (Philadelphia: W.B. Saunders Company, 1994).

4. D.S. Young and E.W. Bermes, "Influence of Site Collection on Blood Gases and pH" in *Tietz Textbook of Clinical Chemistry—Second Edition,* C.A. Burtis and E.R. Ashwood, eds. (Philadelphia: W.B. Saunders Company, 1994).

5. A.S. Relman, "Blood Gases: Arterial or Venous?", in *New England Journal of Medicine,* Vol. 315, No. 3, July 17, 1986, page 188-189.

6. National Committee for Clinical Laboratory Standards, *User Comparison of Quantitative Clinical Laboratory Methods Using Patient Samples; Proposed Guideline* (Villanova, PA: NCCLS, 1986).

7. P.J. Cornbleet and N. Gochman, "Incorrect Least-Squares Regression Coefficients in Method-Comparison Analysis," *Clinical Chemistry* 25:3, 432 (1979).

8. National Committee for Clinical Laboratory Standards, *"Definitions of Quantities and Conventions Related to Blood, pH and Gas Analysis—Second Edition"*; Tentative Standard (1991).

pH

pH is measured by direct potentiometry. In the calculation of results for pH, concentration is related to potential through the Nernst equation. Results are reported at 37ÞC. The performance characteristics of the sensors are equivalent in all cartridge configurations.

See below for information on factors affecting results. Certain substances, such as drugs, may affect analyte levels *in vivo*.[1]

If results appear inconsistent with the clinical assessment, the patient sample should be retested using another cartridge.

Intended Use

The test for pH, as part of the i-STAT System, is intended for use in the *in vitro* quantification of arterial, venous, or capillary whole blood.

Contents

Each i-STAT cartridge contains one reference electrode (when potentiometric sensors are included in the cartridge configuration), sensors for measurement of specific analytes and a buffered aqueous calibrant solution of known concentrations. For cartridges that contain a sensor for the measurement of pH, the calibrant solution is buffered to 7.43.

Expected Values

Test/Abbreviation	Units	Reportable Range	Reference Range	
pH		6.50 – 8.00	7.35 – 7.45[2] (arterial)	7.31 – 7.41* (venous)

* Calculated from Siggaard-Andersen nomogram.

Venous samples normally measure 0.01 – 0.03 pH units lower than arterial samples.

For the measurement of pH, the i-STAT System has been calibrated to agree with standard blood gas methods performed on whole blood at 37°C.

The reference range programmed into the analyzer and shown above is intended to be used as a guide for the interpretation of results. Since reference ranges may vary with demographic factors such as age, gender and heritage, it is recommended that reference ranges be determined for the population being tested.

Clinical Significance

pH is an index of the acidity or alkalinity of the blood with an arterial pH of <7.35 indicating an acidemia and >7.45 alkalemia.[3]

Performance Characteristics

The typical performance data summarized below was collected in health care facilities by health care professionals trained in the use of the i-STAT System and comparative methods.

Precision data was collected in multiple sites using the Performance Verification Guideline found in the i-STAT Implementation Guide. Similar results can be expected in future performance studies provided the same experimental design and data analysis procedures are followed. Method comparison data was collected using NCCLS guideline EP5[4]. Venous blood samples were collected in evacuated tubes and arterial samples were collected in blood gas syringes with lithium heparin anticoagulant. All sample were analyzed in duplicate on the i-STAT System and on the comparative methods within 10 minutes of each other. Arterial blood samples were collected from hospital patients in 3cc blood gas syringes and were analyzed in duplicate on the i-STAT-System and the Radiometer ABL500 within 5 minutes of each other.

Deming regression analysis[5] was performed on the first replicate of each sample. In the method comparison table, n is the number of specimens in the data set, Sxx and Syy refer to estimates of imprecision based on the duplicates of the comparative and the i-STAT methods respectively, Sy.x is the standard error of the estimate, and r is the correlation coefficient.*

Method comparisons will vary from site to site due to differences in sample handling, comparative method calibration and other site specific variables.

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* The usual warning relating to the use of regression analysis is summarized here as a reminder: For any analyte, "if the data is collected over a narrow range, the estimate of the regression parameters are relatively imprecise and may be biased. Therefore, predictions made from these estimates may be invalid".[4] The correlation coefficient, r, can be used as a guide to assess the adequacy of the comparative method range in overcoming this problem. As a guide, the range of data can be considered adequate if $r>0.975$.

Factors Affecting Results

Venous stasis (prolonged tourniquet application) and forearm exercise may decrease pH due to localized production of lactic acid. Exposing the sample to air will cause an increase in pH due to the loss of CO_2. pH decreases on standing anaerobically at room temperature at a rate of 0.03 pH units per hour.[3]

Precision Data

Aqueous Control	Mean	SD	%CV
Level 1	7.165	0.005	0.08
Level 3	7.656	0.003	0.04

Method Comparison

	IL BGE	Radiometer ICA 1	Nova STAT Profile 5	Radiometer ABL500
n	62	47	57	45
Sxx	0.005	0.011	0.006	0.004
Syy	0.009	0.008	0.008	0.008
Slope	0.974	1.065	1.058	1.0265
Int't	0.196	-0.492	-0.436	-0.1857
Sy.x	0.012	0.008	0.010	0.0136
Xmin	7.210	7.050	7.050	
Xmax	7.530	7.570	7.570	
r	0.985	0.990	0.9920	.986

References

1. D.S. Young, *Effects of Drugs on Clinical Laboratory Tests,* 3rd ed. (Washington, DC: American Association of Clinical Chemistry, 1990).

2. P.C. Painter, J.Y. Cope, J.L. Smith, *"Reference Ranges, Table 41–20" in Tietz Textbook of Clinical Chemistry—Second Edition,* C.A. Burtis and E.R. Ashwood, eds. (Philadelphia: W.B. Saunders Company, 1994).

3. E.L. Pruden, O. Siggaard-Andersen, and N.W. Tietz, *Blood Gases and pH,* in Tietz Textbook of Clinical Chemistry, Second Edition, ed. C.A. Burtis and E.R. Ashwood. (Philadelphia: W.B. Saunders Company, 1994.

4. National Committee for Clinical Laboratory Standards, *User Comparison of Quantitative Clinical Laboratory Methods Using Patient Samples; Proposed Guideline* (Villanova, PA: NCCLS, 1986).

5. P.J. Cornbleet and N. Gochman, "Incorrect Least-Squares Regression Coefficients in Method-Comparison Analysis," *Clinical Chemistry* 25:3, 432 (1979).

PCO_2 and calculated values for HCO_3, TCO_2, Base Excess and Anion Gap

PCO_2 is measured by direct potentiometry. In the calculation of results for PCO_2, concentration is related to potential through the Nernst equation. Results are measured at 37°C when using cartridges that require thermal control and corrected to 37°C when using cartridges that do not require thermal control. The performance characteristics of the sensors are equivalent in all cartridge configurations.

Calculated Values

When a cartridge includes sensors for both pH and PCO_2, bicarbonate (HCO_3), total carbon dioxide (TCO_2) and base excess (BE) can be calculated.[1]

$$\log HCO_3 = pH + \log PCO_2 - 7.608$$
$$TCO_2 = HCO_3 + 0.03\ PCO_2$$

$$BE_{ecf} = HCO_3 - 24.8 + 16.2\ (pH - 7.4)$$

When a cartridge includes sensors for sodium, potassium, chloride,
pH and PCO_2, anion gap can be calculated.

$$\text{Anion Gap} = (Na + K) - (Cl + HCO_3)$$

See below for information on factors affecting results. Certain substances, such as drugs, may affect analyte levels *in vivo*.[2] If results appear inconsistent with the clinical assessment, the patient sample should be retested using another cartridge.

Intended Use

The test for PCO_2, as part of the i-STAT System, is intended for use in the *in vitro* quantification of arterial, venous, or capillary whole blood.

Contents

Each i-STAT cartridge contains one reference electrode (when potentiometric sensors are included in the cartridge configuration); sensors for measurement of specific analytes and a buffered aqueous calibrant solution of known concentrations. For cartridges that contain a sensor for the measurement of PCO_2, the calibrant solution contains 30mm Hg of PCO_2.

Expected Values

Test/Abbreviation	Units	Reportable Range	Reference Range	
			(arterial)	(venous)
Partial Pressure Carbon Dioxide/PCO_2	mm Hg	5 - 130	35 - 45[3]	41 - 51
	kPa	0.67 - 17.330	4.67 - 6.00	5.47 - 6.80
Bicarbonate/HCO_3	mmol/L	1 - 85	22 - 26*	23 - 28*
Total Carbon Dioxide/TCO_2	mmol/L	1 - 85	23 - 27*	24 - 29*
Base Excess/BE	mmol/L	(-30) - (+30)	(-2) - (+3)[3]	(-2) - (+3)[3]
Anion Gap/AnGap	mmol/L	(-10) - (+99)	10 - 20[3]	10 - 20[3]

*Calculated from Siggaard-Andersen nomogram.

For TCO_2, values measured on serum or plasma by chemistry analyzers may be slightly lower than TCO_2 calculated from pH and PCO_2 due to loss of CO_2 during non-anaerobic handling.[5] Up to 6mmol/L CO_2 can be lost per hour by exposure of the sample to air.[6]

For the measurement of PCO_2, the i-STAT System has been calibrated to agree with standard blood gas methods performed on whole blood at 37°C.

The reference ranges programmed into the analyzer and shown above are intended to be used as guides for the interpretation of results. Since reference ranges may vary with demographic factors such as age, gender and heritage, it is recommended that reference ranges be determined for the population being tested.

Clinical Significance

PCO_2 along with pH is used to assess acid-base balance. PCO_2 (partial pressure of carbon dioxide), the respiratory component of acid-base balance, is a measure of the tension or pressure of carbon dioxide dissolved in the blood. PCO_2 represents the balance between cellular production of CO_2 and ventilatory removal of CO_2 and a change in PCO_2 indicates an alteration in this balance. Causes of primary respiratory acidosis (increase in PCO_2) are airway obstruction, sedatives and anesthetics, respiratory distress syndrome, and chronic obstructive pulmonary disease. Causes of primary respiratory alkalosis (decreased PCO_2) are hypoxia (resulting in hyperventilation) due to chronic heart failure, edema and neurologic disorders, and mechanical hyperventilation.

HCO_3 (bicarbonate), the most abundant buffer in the blood plasma, is an indicator of the buffering capacity of blood. Regulated primarily by the kidneys, HCO_3 is the metabolic component of acid-base balance. Causes of primary metabolic acidosis (decrease in HCO_3) are ketoacidosis, lactate acidosis (hypoxia), and diarrhea. Causes of primary metabolic alkalosis (increase in HCO_3) are vomiting and antacid treatment.

TCO_2 (total carbon dioxide) is either measured on plasma by automated chemistry analyzers or is calculated from pH and PCO_2 measured on whole blood gas analyzers. TCO_2 is a measure of carbon dioxide which exists in several states: CO_2 in physical solution or loosely bound to proteins, HCO_3 or CO_3 ions, and carbonic acid (H_2CO_3). Bicarbonate ions make up all but approximately 2mmol/L of the total carbon dioxide of plasma. Measurement of TCO_2 as part of an electrolyte profile is useful chiefly to evaluate HCO_3 concentration. TCO_2 and HCO_3 are useful in the assessment of acid-base imbalance (along with pH and PCO_2) and electrolyte imbalance.

Base excess of the extracellular fluid or standard base excess is defined as the concentration of titratable base minus the concentration of titratable acid when titrating the average intracellular fluid (plasma plus interstitial fluid) to an arterial plasma pH of 7.40 at PCO_2 of 40 mm Hg at 37°C. Excess concentration of base in the average ECF remains virtually constant during acute changes in the PCO_2 and reflects only nonrespiratory component of pH-disturbances.

Anion gap is reported as the difference between the commonly measured cations sodium and potassium and the commonly measured anions chloride and bicarbonate. The size of the gap reflects unmeasured cations and anions and is therefore an analytical gap. Physiologically, a deficit of anions cannot exist. While relatively nonspecific, anion gap is useful for the detection of organic acidosis due to an increase in anions that are difficult to measure. Anion gap can be used to classify metabolic acidosis into high and normal anion gap types. Anion gap may be only slightly increased in diarrhea and renal failure, but elevated (often >25) due to an increase in organic anions in lactic acidosis, ketoacidosis (alcoholic, diabetic, starvation) and uremia, an increase in inorganic anions in uremia, and an increase in anions from drugs such a salicylate and carbenicillin or toxins such as methanol and ethanol.

Performance Characteristics

The typical performance data summarized below was collected in a health care facility by health care professionals trained in the use of the i-STAT System and comparative methods.

Precision data was collected in multiple sites using the Performance Verification Guideline found in the i-STAT Implementation Guide. Similar results can be expected in future performance studies provided the same experimental design and data analysis procedures are followed. Method comparison data was collected using NCCLS guideline EP5.[7] Venous blood samples were collected in blood gas syringes. To measure TCO_2, the sample was centrifuged to obtain plasma. All samples were analyzed in duplicate on the i-STAT System and on the comparative methods within 10 minutes of each other.

Arterial blood samples were collected from hospital patients in 3cc blood gas syringes and were analyzed in duplicate on the i-STAT System and the Radiometer ABL500 within 5 minutes of each other.

Deming regression analysis[8] was performed on the first replicate of each sample. In the method comparison table, n is the number of specimens in the data set, Sxx and Syy refer to estimates of imprecision based on the duplicates of the comparative and the i-STAT methods respectively, Sy.x is the standard error of the estimate, and r is the correlation coefficient.*

Method comparisons will vary from site to site due to differences in sample handling, comparative method calibration and other site specific variables.

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* The usual warning relating to the use of regression analysis is summarized here as a reminder: For any analyte, "if the data is collected over a narrow range, the estimate of the regression parameters are relatively imprecise and may be biased. Therefore, predictions made from these estimates may be invalid".[7] The correlation coefficient, r, can be used as a guide to assess the adequacy of the comparative method range in overcoming this problem. As a guide, the range of data can be considered adequate if r>0.975.

Factors Affecting Results*

Exposing the sample to air allows CO_2 to escape which causes PCO_2 to decrease and pH to increase and HCO_3 and TCO_2 to be under-estimated.

Allowing blood to stand (without exposure to air) before testing allows PCO_2 to increase and pH to decrease, which will cause HCO_3 and TCO_2 to be over-estimated, due to metabolic processes.

Interferent	Effect
Propofol (Diprivan®)	Procedures that involve sustained (>1hour) administration of propofol at rates in excess of 50 µg/kg/min (3 mg/kg/hour) may result in significant errors in i-STAT PCO_2 results (see Note 1 below). Alternately, such administration may result in the automated suppression of PCO_2 and pH values (*** displayed) by the analyzer's quality system. Use an alternative method to measure PCO_2 when administering propofol at rates in excess of this level. Consider an alternative method when administering propofol at any sustained rate to patients with renal impairment. See Note 3 for an alternative offered by i-STAT.
Thiopental Sodium	Sustained administration (over more than a few minutes) of thiopental sodium, either by continuous or intermittent drips, may result in plasma concentrations of thiopental sodium that yield significant errors in i-STAT PCO_2 results (see Note 2 below). Alternately, such administration may result in the automated suppression of PCO_2 and pH values (*** displayed) by the analyzer's quality system. Use an alternate method to measure PCO_2 when administering thiopental sodium on a sustained basis. See Note 3 for an alternative offered by i-STAT.

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* It is possible that other interfering substance may be encountered. These results are representative and your results may differ somewhat due to test-to-test variation. The degree of interference at concentrations other than those listed might not be predictable.

Notes:

1) Propofol is an intravenous sedative-hypnotic agent. Among its applications are the induction and maintenance of anesthesia and the sedation of intubated, mechanically ventilated patients. Although propofol itself does not directly interfere with the measurement of PCO_2 on the i-STAT System, decreases in PCO_2 of > 5 mmHg (0.67 kPa) have been observed on some patients due to metabolic byproducts of propofol, as a result of sustained (>1hr) administration at rates in excess of 50 µg/kg/min (3 mg/kg/hour). At doses of 50-100 µg/kg/min (3-6mg/kg/hour) some errors as large as 10 mmHg or 1.33 kPa.(below 40 mmHg or 5.33 kPa) or 25% (above 40 mmHg or 5.33 kPa) were observed. At doses significantly above 100 µg/kg/min (6 mg/kg/hour) we have observed errors as large as 40% for administration in excess of 5 hours, although more typically results were suppressed by the analyzer (***displayed). Below 50 µg/kg/min, decreases are typically less than 3 mmHg but sometimes as large as 5 mmHg (0.67 kPa). We have observed no decreases when a single dose of propofol is administered to induce anesthesia. We advise caution, however, when administering propofol to any patient with renal impairment as this may affect the clearance rate of metabolic byproducts.

2) Thiopental Sodium (*syn.* thiomebumal sodium, penthiobarbital sodium, thiopentone sodium, thionembutal, Pentothal Sodium®, Nesdonal Sodium®, Intraval Sodium®, Trapanal®, and Thiothal Sodium[9]) is an ultra-short-acting, intravenous anesthetic. It is used as an induction agent for general anesthesia, to control status epilepticus, in the treatment of intracranial hypertension, and in narcoanalysis of psychiatric disorders. Sustained administration (over more than a few minutes) of thiopental sodium may lead to >5 mmHg (0.67 kPa) decreases in PCO_2 results. Errors observed on patient samples have been as large as 20 mmHg (2.67 kPa). For single dose administration of thiopental given over a few minutes, such as in the induction of anesthesia, interference on the i-STAT PCO_2 is modest (<10% at 40 mmHg or 5.33 kPa, <15% at 70 mmHg or 9.33 kPa) approximately 15 minutes after administration of typical doses, since thiopental is rapidly absorbed from the bloodstream, falling below 10 µg/mL within 15 minutes[10]. The interference will continue to diminish as the drug continues to be absorbed.

(3) The interference affects cited above refer to the expected i-STAT System performance using analyzers with **standard software**:

- JAMSxxx with CLEW Axx in the i-STAT Portable Clinical Analyzer (except Japan), i-STAT 1 Analyzer and i-STAT 300F Analyzer. ('x' indicates any alphanumeric character.)
- JAMSxxx with CLEW Cxx in the i-STAT Portable Clinical Analyzer in Japan.
- HPxxxxx with CLEW Hxx (Jxx in Japan) in the Agilent Technologies Blood Analysis Module.

i-STAT offers an **alternative version** of software that reduces the interference effect of propofol and thiopental by about 2.5 times relative to that observed with the standard software.

- MINTxxx with CLEW Dxx in the i-STAT Portable Clinical Analyzer (except Japan), i-STAT 1 Analyzer and i-STAT 300F Analyzer. ('x' indicates any alphanumeric character.)
- MINTxxx with CLEW Exx in the i-STAT Portable Clinical Analyzer in Japan.
- MNxxxxx with CLEW Nxx (Vxx in Japan) in the Agilent Technologies Blood Analysis Module.

Software version MINTxxx/Dxx (or MNxxxxx/Nxx) reduces interference effects by reducing the temperature of the PCO_2 measurement from 37°C to 30°C. When MINTxxx or MNxxxxx is in use, all references in the i-STAT product literature to sensor, test, or cartridge temperature control to 37°C should be interpreted to indicate temperature control of PCO_2 and pH measurements to 30°C (all other analytes are measured as they are in the standard software). The reported PCO_2 and pH results have been corrected to their 37°C values. When using this software, the following interference affects are observed:

Interferent	**Effect (*Software version MINTxxx/Dxx/Exx or MNxxxxx/Nxx/Vxx only*)**
Propofol (Diprivan®)	Sustained administration of propofol over >5 hours at rates in excess of 90 µg/kg/min (5.4 mg/kg/hour) may result in significant errors (>5 mmHg or 0.67 kPa) in i-STAT PCO_2 results. Alternately, such administration may result in the automated suppression of PCO_2 and pH results (*** displayed) by the analyzer's quality system. Consider an alternate method when administering propofol at rates in excess of this level. Use caution in the interpretation of results or consider an alternate method to measure PCO_2 when administering propofol at any sustained rate to patients with renal impairment.
Thiopental Sodium	Sustained administration (over more than a few minutes) of thiopental sodium, either by continuous or intermittent drips, may result in plasma concentrations of thiopental sodium that yield significant errors (>5 mmHg or 0.67 kPa) in i-STAT PCO_2 results. Alternately, such administration may result in the automated suppression of PCO_2 and pH results (*** displayed) by the analyzer's quality system. For single dose administration over a few minutes, such as in the induction of anesthesia, interference is modest (<4% at 40 mmHg or 5.33 kPa, <6% at 70 mmHg or 9.33 kPa) approximately 15 minutes after administration of typical doses. Use caution in the interpretation of results or consider an alternate method to measure PCO_2 when administering thiopental sodium on a sustained basis.

When using the alternate software, **the analyzer operating temperature range for running cartridges is restricted to 16-28°C**, instead of the standard 16-30°C as stated in the product literature. With the exception of this and the interference characteristics stated above, the i-STAT System with the alternative MINTxxxx/Dxx or MNxxxx/Nxx software version is equivalent to that of the standard system. To facilitate management of the i-STAT System when both versions of software are used in a single facility, note that the software version in an analyzer is displayed on the status page of the analyzer. The CLEW version is on printouts from the handheld analyzer and is also transmitted to the i-STAT Central Data Station and stored in the database.

Precision Data (mmHg)

Aqueous Control	Mean	SD	%CV
Level 1	63.0	1.72	2.73
Level 3	19.4	0.70	3.59

Method Comparison (mmHg)

	PCO_2 IL BGE	TCO_2 IL BGE	TCO_2 Beckman CX®3	Radiometer ABL500
n	62	62	51	45
Sxx	0.69	0.40	0.55	0.549
Syy	1.24	0.84	0.55	1.059
Slope	1.003	1.136	1.155	0.958
Int't	-0.8	-4.1	-2.6	1.036
Sy.x	1.65	1.38	1.56	11.460
Xmin	30.4	19.3	18.3	
Xmax	99.0	43.9	36.1	
r	0.989	0.965	0.935	0.995

References

1. NCCLS. *Blood Gas and pH Analysis and Related Measurements; Proposed Guidelines.* NCCLS document C46-P [ISBN 1-56238-399-X]. NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA 2000.

2. D.S. Young, *Effects of Drugs on Clinical Laboratory Tests,* 3rd ed. (Washington, DC: American Association of Clinical Chemistry, 1990).

3. P.C. Painter, J.Y. Cope, J.L. Smith, *"Reference Ranges, Table 41–20" in Tietz Textbook of Clinical Chemistry—Second Edition,* C.A. Burtis and E.R. Ashwood, eds. (Philadelphia: W.B. Saunders Company, 1994).

4. E.L. Pruden, O. Siggaard-Andersen, and N.W. Tietz, *Blood Gases and pH,* in Tietz Textbook of Clinical Chemistry, Second Edition, ed. C.A. Burtis and E.R. Ashwood. (Philadelphia: W.B. Saunders Company).

5. J.P.J. Ungerer, M.J. Ungerer, and W.J.H Vermaak, Discordance Between Measured and Calculated Total Carbon Dioxide, Clinical Chemistry 36.12, 1990. 2093-2096.

6. N.W. Tietz, E.L. Pruden, O. Siggaard-Andersen, Electrolytes, in Tietz Textbook Clinical Chemistry Second Edition, ed. C.A. Burtis and E.R. Ashwood. (Philadelphia: W.B. Saunders Company 1994).

7. NCCLS. *Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline.* NCCLS document EP9-A [ISBN 1-56238-283-7]. NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA 1995.

8. P.J. Cornbleet and N. Gochman, "Incorrect Least-Squares Regression Coefficients in Method-Comparison Analysis," *Clinical Chemistry* 25:3, 432 (1979).

9. The Merck Index, Eleventh Edition, Merck & Co., Inc, NJ, 1989.

10. P.G. Burgh and D.R. Stanski, Anesthesiology, 58:146-152, 1983.

i-STAT is a registered trademark of i-STAT Corporation, East Windsor, NJ USA.

CX®3 is a registered trademark of Beckman Instruments, Inc., Brea, CA USA.

Diprivan is a registered trademark of the AstraZeneca group of companies.

Pentothal Sodium is a registered trademark of Abbott Labs., USA.

Nesdonal Sodium is a registered trademark of Specia, France.

Intraval Sodium is a registered trademark of May and Baker, Ltd., England.

Trapanal is a registered trademark of Chemische Fabrik Promonta, Germany.

CREATININE/CREA

Creatinine is hydrolyzed to creatine in a reaction catalyzed by the enzyme creatinine amidohydrolase. Creatine is then hydrolyzed to sarcosine in a reaction catalyzed by the enzyme creatine amidinohydrolase. The oxidation of sarcosine, catalyzed by the enzyme sarcosine oxidase, produces hydrogen peroxide (H_2O_2). The liberated hydrogen peroxide is oxidized at the platinum electrode to produce a current which is proportional to the sample creatinine concentration.

$$\text{Creatinine} + H_2O \xrightarrow{\text{Creatinine Amidohydrolase}} \text{Creatine}$$
$$\text{Creatine} + H_2O \xrightarrow{\text{Creatine Amidinohydrolase}} \text{Sarcosine} + \text{Urea}$$
$$\text{Sarcosine} + O_2 + H_2O \xrightarrow{\text{Sarcosine Oxidase}} \text{Glycine} + \text{Formaldehyde} + H_2O_2$$
$$H_2O_2 \longrightarrow O_2 + 2H^+ + 2e^-$$

See below for information on factors affecting results. Certain substances, such as drugs, may affect analyte levels *in vivo*.[1] If results appear inconsistent with the clinical assessment, the patient sample should be retested using another cartridge.

INTENDED USE

The test for creatinine, as part of the i-STAT System, is intended for use in the *in vitro* quantification of creatinine in arterial, venous, or capillary whole blood.

Contents

Each i-STAT cartridge contains one reference electrode (when potentiometric sensors are included in the cartridge configuration), sensors for measurement of specific analytes and a buffered aqueous calibrant solution of known concentrations. For cartridges that contain a sensor for the measurement of creatinine, the calibrant solution contains 2.2 mg/dL (194 µmol/L) of creatinine.

Expected Values

Test/Abbreviation	Units	Reportable Range	Reference Range
Creatinine/Crea	mg/dL	0.2 – 20.0	0.6 – 1.3[2]
	µmol/L	18 – 1768	53 – 115

To convert a creatinine result from mg/dL to µmol/L, multiply the displayed creatinine result by 88.4.*

i-STAT measurements are performed on whole blood specimens. The i-STAT System has been calibrated to agree with standard laboratory and reference methods typically performed on serum and plasma. Therefore, the reference ranges presented above are equivalent to reference ranges derived from serum or plasma measurements with standard laboratory methods.

The reference range programmed into the analyzer and shown above is intended to be used as a guide for the interpretation of results. Since reference ranges may vary with demographic factors such as age, gender and heritage, it is recommended that reference ranges be determined for the population being tested.

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* The i-STAT System can be configured with the preferred units.

Clinical Significance

Elevated levels of creatinine are mainly associated with abnormal renal function and occur whenever there is a significant reduction in glomerular filtration rate or when urine elimination is obstructed. The concentration of creatinine is a better indicator of renal function than urea or uric acid because it is not affected by diet, exercise, or hormones.

The creatinine level has been used in combination with BUN to differentiate between prerenal and renal causes of an elevated urea/BUN.

Performance Characteristics

The typical performance data summarized below were collected in health care facilities by professionals trained in the use of the i-STAT System and comparative methods.

Precision data were collected in multiple sites using the Performance Verification Guideline found in the i-STAT Implementation Guide. Similar results can be expected in future performance studies provided the same experimental design and data analysis procedures are followed. Method comparison data were collected using NCCLS guideline EP5[3]. Venous blood samples, collected in lithium or sodium heparin Vacutainer® tubes, and arterial blood samples, collected in blood gas syringes, were analyzed in duplicate on the i-STAT System. A portion of each specimen was centrifuged, and the separated plasma was analyzed on the comparative method.

Deming regression analysis[4] was performed on the first replicate of each sample. In the method comparison table, n is the number of specimens in the data set, Sxx and Syy refer to the estimates of imprecision based on the duplicates of the comparative and the i-STAT methods respectively, Sy.x is the standard error of the estimate, and r is the correlation coefficient.*

Interference studies were based on NCCLS guideline EP7.[5]

*The usual warning relating to the use of regression analysis is summarized here as a reminder: For any analyte, "if the data is collected over a narrow range, the estimate of the regression parameters are relatively imprecise and may be biased. Therefore, predictions made from these estimates may be invalid".[3] The correlation coefficient, r, can be used as a guide to assess the adequacy of the comparative method range in overcoming this problem. As a guide, the range of data can be considered adequate if r>0.975.

Factors Affecting Results*

Interferent	Effect
Bromide	100 mg/dL (12.5 mM/L) bromide will increase creatinine by 0.8 mg/dL (71 µmol/L) from an initial creatinine concentration of 1.0 mg/dL (88µmol/L).
CO_2	PCO_2 values above 40 mmHg at 37°C will increase creatinine results by approximately 3.8% per 10 mmHg PCO_2. PCO_2 values below 40 mmHg will decrease creatinine by approximately 3.8% per 10 mmHg PCO_2.
Hydroxyurea (Droxia®, Hydrea®)	Hydroxyurea may cause significant errors in the measurement of creatinine with the i-STAT System. Use an alternative method to measure creatinine when patients have been administered hydroxyurea. See note (1) below for typical uses of this drug and note (2) below for details of the interference.

*It is possible that other interfering substance may be encountered. These results are representative and your results may differ somewhat due to test-to-test variation. The degree of interference at concentrations other than those listed might not be predictable.

Notes:

1) Hydroxyurea is a DNA synthesis inhibitor used in the treatment of various forms of cancer, sickle cell anemia, and HIV infection. This drug is used to treat malignancies including melanoma, metastatic ovarian cancer, and chronic myelogenous leukemia. It is also used in the treatment of polycythemia vera, thrombocytopenia, and psoriasis. At typical doses ranging from 500 mg to 2 g/day, concentrations of hydroxyurea in patients' blood may be sustained at approximately 100 to 500 µmol/L. Higher concentrations may be observed soon after dosing or at higher therapeutic doses.

2) For every 100 µmol/L hydroxyurea in the whole blood sample, creatinine will be increased by approximately 1.85 mg/dL (164 µmol/L), up to a whole blood hydroxyurea concentration of at least 921 µmol/L (maximum concentration tested). The magnitude of the bias is independent of the creatinine level over a range of at least 1.0 mg/dL (88 µmol/L) to 12.4 mg/dL (1096 µmol/L).

Acetaminophen up to 20 mg/dL, ascorbate up to 3.0 mg/dL, bicarbonate up to 40 mmol/L, bilirubin up to 20 mg/dL, calcium up to 5.0 mg/dL, dopamine up to 13 mg/dL, methyldopa up to 2.5 mg/dL, salicylate up to 50 mg/dL, sarcosine up to 1.0 mM/L, and uric acid up to 20 mg/dL were tested and found not to interfere with creatinine results.

Precision Data

Aqueous Control	n	Mean	SD	%CV
Level 1	78	4.4	0.08	1.82
Level 3	78	0.6	0.06	10.0

Method Comparison

	Hitachi 917	J&J Vitros
n	67	48
Sxx	0.045	0.035
Syy	0.087	0.109
Slope	1.002	1.005
Int't	0.030	-0.109
Sy.x	0.110	0.229
Xmin	0.3	0.5
Xmax	11.2	12.6
r	0.9987	0.9931

References

1. D. S. Young, *Effects of Drugs on Clinical Laboratory Tests*, 3rd ed. (Washington, DC: American Association of Clinical Chemistry, 1990).

2. B. E. Statland, *Clinical Decision Levels for Lab Tests*, 2nd ed. (Oradell, NJ: Medical Economics Company, Inc., 1987).

3. NCCLS. *Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline.* NCCLS document EP9-A [ISBN 1-56238-283-7]. NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA 1995.

4. P.J. Cornbleet and N. Gochman, "Incorrect Least-Squares Regression Coefficients in Method Comparison Analysis," *Clinical Chemistry* 25:3, 432 (1979).

5. NCCLS. *Interference Testing in Clinical Chemistry; Proposed Guideline.* NCCLS document EP7-P (ISBN 1-56238-020-6). NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087, 1986.

Droxia and Hydrea are registered trademarks of Bristol-Myers Squibb Company, Princeton, NJ.

LACTATE/Lac

The enzyme lactate oxidase, immobilized in the lactate biosensor, selectively converts lactate to pyruvate and hydrogen peroxide (H_2O_2). The liberated hydrogen peroxide is oxidized at the platinum electrode to produce a current which is proportional to the sample lactate concentration.

$$\text{L-Lactate} + O_2 \xrightarrow{\text{Lactate Oxidase}} \text{Pyruvate} + H_2O_2$$

$$H_2O_2 \xrightarrow{\text{Platinum electrode}} 2H^+ + O_2 + 2e^-$$

See below for information on factors affecting results. Certain substances, such as drugs, may affect analyte levels *in vivo.*[1] If results appear inconsistent with the clinical assessment, the patient sample should be retested using another cartridge.

Intended Use

The test for lactate, as part of the i-STAT System, is intended for use in the *in vitro* quantification of lactate in arterial, venous, or capillary whole blood.

Contents

Each i-STAT cartridge contains one reference electrode (when potentiometric sensors are included in the cartridge configuration), sensors for measurement of specific analytes and a buffered aqueous calibrant solution of known concentrations. The calibrant solution contains 2.00 mmol/L (18.0 mg/dL) of lactate.

Expected Values

Test/Abbreviation	Units*	Reportable Range	Reference[2] Range (arterial)	Reference[2] Range (venous)
Lactate/Lac	mmol/L	0.30 – 20.00	0.36 – 1.25	0.90 – 1.70
	mg/dL	2.7 – 180.2	3.2 – 11.3	8.1 – 15.3

To convert a lactate result from mmol/L to mg/dL, multiply the displayed lactate result by 9.01.

i-STAT measurements are performed on whole blood specimens. The i-STAT System has been calibrated to agree with standard laboratory and reference methods typically performed on whole blood. Therefore, the reference ranges presented above are equivalent to reference ranges derived from whole blood measurements with standard laboratory methods.

The reference range shown above is intended to be used as a guide for the interpretation of results. Since reference ranges may vary with demographic factors such as age, gender and heritage, it is recommended that reference ranges be determined for the population being tested.

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* The i-STAT System can be configured with the preferred units.

Clinical Significance

Elevated levels of lactate are mainly found in conditions of hypoxia such as shock, hypovolumia, and left ventricular failure; in conditions associated with diseases such as diabetes mellitus, neoplasia, and liver disease; and in conditions associated with drugs or toxins such as ethanol, methanol, or salicylates.[2]

Performance Characteristics

The typical performance data summarized below was collected in health care facilities by health care professionals trained in the use of the i-STAT System and comparative methods.

Precision data was collected essentially using the Performance Verification protocol recommended by i-STAT Corporation. Similar results can be expected in future performance studies provided the same experimental design and data analysis procedures are followed. Method comparison data was collected using NCCLS guideline EP5[3]. Venous blood samples, collected in sodium heparin Vacutainer® tubes, and arterial blood samples, collected in blood gas syringes, were analyzed in duplicate on the i-STAT System. In the plasma study, a portion of each specimen was centrifuged, and the separated plasma was analyzed on the comparative method.

Deming regression analysis[4] was performed on the first replicate of each sample. In the method comparison table, n is the number of specimens in the data set, Sxx and Syy refer to the estimates of imprecision based on the duplicates of the comparative and the i-STAT methods respectively, Sy.x is the standard error of the estimate, and r is the correlation coefficient.*

Interference studies were based on NCCLS guideline EP7.[5]

*The usual warning relating to the use of regression analysis is summarized here as a reminder: For any analyte, "if the data is collected over a narrow range, the estimate of the regression parameters are relatively imprecise and may be biased. Therefore, predictions made from these estimates may be invalid".[3] The correlation coefficient, r, can be used as a guide to assess the adequacy of the comparative method range in overcoming this problem. As a guide, the range of data can be considered adequate if r>0.975.

Factors Affecting Results*

Special collection procedures are necessary to prevent changes in lactate both during and after the blood is drawn. For steady state lactate concentrations, patients should be at rest for 2 hours and fasting. Venous samples should be obtained without the use of a tourniquet or immediately after the tourniquet is applied. Both venous and arterial samples may be collected into heparinized syringes.

Samples for lactate should be analyzed immediately on drawing as lactate increases by as much as 70% within 30 minutes at 25 °C as a result of glycolysis.[2]

Interferent	Effect
Bromide	25 mmol/L (200 mg/dL) bromide will decrease lactate results by 40%.
Cysteine	6.4 mmol/L (101 mg/dL) cysteine will decrease lactate results by 15%.
Hydroxyurea (Droxia®, Hydrea®)	Hydroxyurea may cause significant errors in the measurement of lactate with the i-STAT System. Consider using an alternative method to measure lactate when patients have been administered hydroxyurea. See note (1) below for typical uses of this drug and note (2) below for details of the interference.

Droxia and Hydrea are registered trademarks of Bristol-Meyers Squibb Company, Princeton, NJ.

*It is possible that other interfering substance may be encountered. These results are representative and your results may differ somewhat due to test-to-test variation. The degree of interference at concentrations other than those listed might not be predictable.

Notes:

1) Hydroxyurea is a DNA synthesis inhibitor used in the treatment of various forms of cancer, sickle cell anemia, and HIV infection. This drug is used to treat malignancies including melanoma, metastatic ovarian cancer, and chronic myelogenous leukemia. It is also used in the treatment of polycythemia vera, thrombocytopenia, and psoriasis. At typical doses ranging from 500 mg to 2 g/day, concentrations of hydroxyurea in patients' blood may be sustained at approximately 100 to 500 µmol/L. Higher concentrations may be observed soon after dosing or at higher therapeutic doses.

2) For every 100 μmol/L hydroxyurea in the whole blood sample, lactate will be increased by approximately 0.16 mmol/L, up to a whole blood hydroxyurea concentration of at least 921 μmol/L (maximum concentration tested). The magnitude of the bias is independent of the lactate level over a range of at least 2.8 mmol/L to 16.0 mmol/L.

Acetaldehyde up to 0.6 mg/dL (0.14 mM), acetominophen up to 20 mg/dL (1.3 mM), acetylsalicylic acid up to 50 mg/dL (2.8 mM), ascorbic acid up to 3 mg/dL (0.17 mM), ß-hydroxybutyric acid up to 202 mg/dL (16 mM), dopamine up to 13 mg/dL (0.85 mM), formaldehyde up to 1.2 mg/dL (0.40 mM), glycine up to 98 mg/dL (13 mM), pyruvic acid up to 2.6 mg/dL (0.24 mM), and uric acid up to 25 mg/dL (1.5 mM) were tested and found not to interfere with lactate results. Hematocrit levels between 25 and 67% were tested and found not to interfere with lactate results.

Precision Data

Aqueous Control	n	Mean	SD	%CV
Level 1	191	0.66	0.04	6.1
Level 3	196	6.78	0.16	2.4

Method Comparison

	Radiometer ABL 725 (whole blood vs. whole blood)	Hitachi 917 (i-STAT whole blood vs. Hitachi plasma)
n	47	47
Sxx	0.123	0.084
Syy	0.136	0.079
Slope	1.02	1.06
Int't	0.12	-0.32
Sy.x	0.18	0.17
Xmin	0.80	1.77
Xmax	14.20	14.24
r	0.998	0.997

CARTRIDGE INFORMATION

References

1. D.S. Young, *Effects of Drugs on Clinical Laboratory Tests*, 3rd ed. (Washington, DC: American Association of Clinical Chemistry, 1990).

2. D.B. Sacks, *Carbohydrates,* in Tietz Textbook of Clinical Chemistry, Second Edition, ed. C.A. Burtis and E.R. Ashwood, (Philadelphia: W.B. Saunders Company, 1994).

3. NCCLS. *Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline.* NCCLS document EP9-A [ISBN 1-56238-283-7]. NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA 1995.

4. P.J. Cornbleet and N. Gochman, "Incorrect Least-Squares Regression Coefficients in Method Comparison Analysis," *Clinical Chemistry* 25:3, 432 (1979).

5. NCCLS. *Interference Testing in Clinical Chemistry; Proposed Guideline.* NCCLS document EP7-P [ISBN 1-56238-020-6]. NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA 1986.

Droxia and Hydrea are registered trademarks of Bristol-Myers Squibb Company, Princeton, NJ.

CELITE ACTIVATED CLOTTING TIME/($^{\text{Celite}}$ACT)

The i-STAT® Celite® Activated Clotting Time test, $^{\text{Celite}}$ACT, is a measure of the time required for complete activation of the coagulation cascade[1]

In traditional ACT tests, coagulation is initiated by mixing a whole blood sample with a particulate activator, and complete activation is indicated when extensive or localized clots form as activated thrombin converts fibrinogen to fibrin. These clots are mechanically detected.

The i-STAT ACT test is similar to traditional ACT except that the endpoint is indicated by the conversion of a thrombin substrate other than fibrinogen and an electrochemical sensor is used to indicate the event of this conversion. The substrate used in the electrogenic assay has an amide linkage that mimics the thrombin-cleaved amide linkage in fibrinogen.

The substrate is H-D-phenylalanyl-pipecolyl-arginine-*p*-amino-*p*-methoxydiphenylamine which has the structure:

Phenylalanine - Pipecolic acid - Arginine -- NH - C_6H_4 - NH - C_6H_4 - OCH_3

Thrombin cleaves the amide bond at the carboxy- terminus of the arginine residue (denoted by the two dashes) because the bond structurally resembles the thrombin-cleaved amide linkage in fibrinogen. The product of the thrombin-substrate reaction is the electrochemically inert tripeptide Phenylalanyl - Pipecolyl - Arginine and the electroactive compound NH_3^+ - C_6H_4 - NH - C_6H_4 - OCH_3. The formation of the electroactive compound is detected amperometrically, and the time of detection is measured in seconds. The test reports the Activated Clotting Time (ACT) as a whole blood time (WBT) in seconds.

If results appear inconsistent with the clinical assessment, the patient sample should be re-tested using another cartridge.

Intended Use

The i-STAT Celite Activated Clotting Time ($^{\text{Celite}}$ACT) test cartridge, as part of the i-STAT System, is an *in vitro* diagnostic test used to monitor moderate- and high-level heparin therapy through analysis of arterial and venous whole blood samples.

Contents

Each i-STAT $^{\text{Celite}}$ACT cartridge provides a sample collection chamber, sensors to detect the coagulation endpoint and dry reagents necessary to initiate and allow coagulation. These reagents are coated on a section of the sensor channel and include a particulate activator, a thrombin substrate, and stabilizers.

Expected Values

Test/Abbreviation	Units	Reportable Range	Reference Range
Activated Clotting Time/ACT	seconds	50 – 1000*	74 - 125

*The range from 80 - 1000 seconds has been verified through method comparison studies.

Clinical Significance

The ACT is primarily used to monitor a patient's state of anticoagulation due to heparin that is administered during a medical or surgical procedure. It is commonly employed in cardiac catheterization, Percutaneous Transluminal Coronary Angioplasty (PTCA), renal dialysis, hemodialysis, and extra-corporeal circulation during bypass.

Performance Characteristics

The typical performance data summarized below was collected in health care facilities by health care professionals trained in the use of the i-STAT System and comparative methods.

Precision data were collected at i-STAT and during clinical trials following a protocol recommended by i-STAT and using plasma control material. Similar results can be expected in future performance studies provided the same experimental design and data analysis procedures are followed.

Plasma Control	Mean	SD	%CV
Level 1	221 seconds	18 seconds	7.4
Level 2	456 seconds	22 seconds	4.8

Method comparison data were collected using a modification of the NCCLS guidelines[2]. Venous or arterial blood samples were collected in plastic syringes and analyzed in duplicate on the i-STAT System and in duplicate using the comparative methods. All samples were analyzed immediately upon collection. The patient populations in the studies were those in which ACT is routinely used. This includes baseline, heparin-treated, and heparin-reversed samples from patients undergoing catheterization, procedures involving cardiac bypass, PTCA, and renal dialysis.

Deming regression analysis[3] was performed on the first replicate of each sample. In the method comparison table, *n* is the number of specimens in the data set, *Sxx* and *Syy* refer to estimates of the imprecision based on the duplicates of the comparative and i-STAT methods respectively, *Sy.x* is the standard error of the estimate, and *r* is the correlation coefficient.

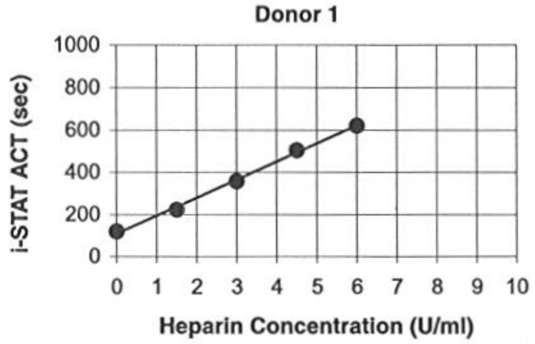
Method comparisons will vary from site to site due to differences in the sample handling, reagent and instrument systems in use, and other site-specific variables.

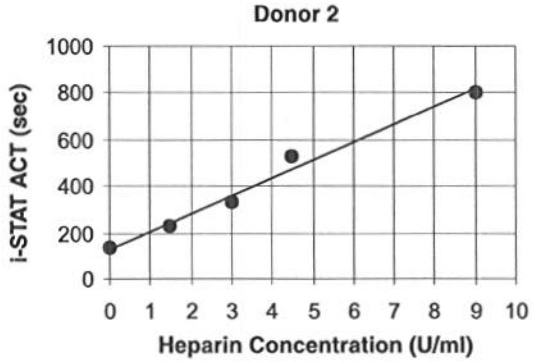
Statistic	i-STAT vs Hemochron Site 1	i-STAT vs Hemochron Site 2	i-STAT vs Hemochron Site 3
n	91	73	101
Syy	57	61	31
Sxx	28	21	30
Sy.x	95	95	55
slope	0.995	1.08	1.01
intercept	-0.3	11	8
Correlation	0.949	0.921	0.949
Range	95 - 987 sec	83 - 1050 sec	100 - 1139 sec

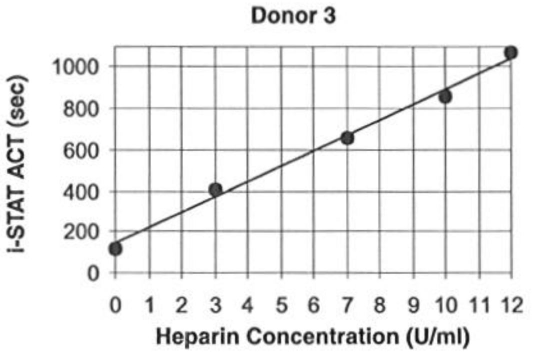
Factors Affecting Results

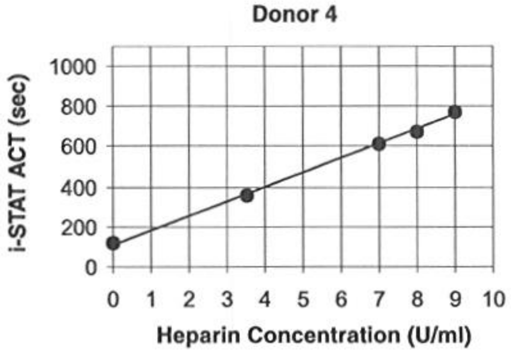
Heparin sensitivity was demonstrated using whole blood samples to which varying concentrations of heparin were added *in vitro.*

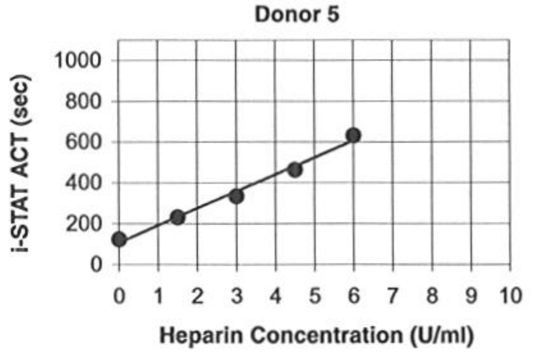
The five graphs below each indicate the response of a different donor with respect to heparin concentration:











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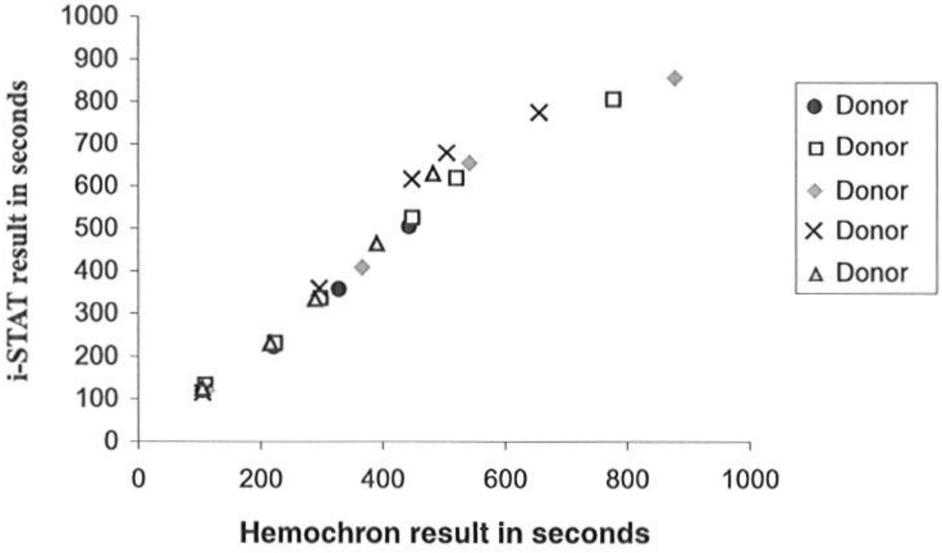
The graph below indicates the response of the same five donors with respect to the ACT result on a comparative instrument:



Test Limitations

The i-STAT CeliteACT test is to be used with fresh venous or arterial whole blood samples. The presence of exogenously added heparin, citrate, oxalate, or EDTA will interfere with test results. Poor technique in sample collection may also compromise the results. Samples drawn from insufficiently flushed catheters or from traumatic venipunctures may be contaminated with interfering substances. Samples should be collected into plastic syringes or tubes. Collection into glass may prematurely activate coagulation resulting in accelerated clotting times.

The i-STAT ACT test uses Celite brand diatomaceous earth as the activator of the intrinsic pathway. The result may, therefore, be prolonged in the presence of aprotinin.[4] **The test is not recommended for use with patients receiving aprotinin.**

The analyzer should remain on a flat surface with the display facing up during testing. If the analyzer is not level, the ACT result may be extended by more than 10%.

Hemodilution may affect results; however, this effect on the i-STAT CeliteACT result has been determined to be approximately one-third that of automated mechanical detection methods.

Platelet dysfunction, factor deficiencies, dysprothrombinemias, pharmacological compounds, and other coagulopathies may affect the results of this test.

The i-STAT ACT test is not affected by hematocrit in the range of 20 - 70%, fibrinogen concentration in the range from 100 - 500 mg/dL, or sample temperature from 15 - 37°C.

Storage Instructions

Cartridges in sealed pouches are stable through the expiration date when stored refrigerated at 2 to 8°C and for two weeks at room temperature (18 - 30°C).

Upon removal from refrigeration, a box of 25 cartridges requires one hour equilibration at room temperature before use. Individual cartridges require five minutes equilibration. A cartridge should be used immediately after it is removed from the pouch.

Quality Control

On a daily basis, the performance of all Analyzers in the i-STAT System on site should be verified using the i-STAT Electronic Simulator.

On receipt of new cartridges, verify that the transit temperatures were satisfactory using the four-window temperature indicator strip included with the cartridge boxes. From each shipment of cartridges, analyze multiple levels of i-STAT ACT Controls using any verified Analyzer. Instructions for the use of these controls are found in the i-STAT System Manual and should be followed.

For additional information on Quality Control of the i-STAT System, refer to the "Quality Control" section (Section 5) of the "Operating Instructions" found in the i-STAT System Manual.

Specimen Collection and Preparation

The i-STAT $^{\text{Celite}}$ACT test can be performed using venous or arterial samples.

Venipunctures and Arterial Punctures

- Collection technique resulting in good blood flow must be used.
- The sample for testing should be drawn into a **plastic collection device** (either a plastic syringe or plastic evacuated tube).
- The collection device **cannot contain anticoagulants** such as heparin, EDTA, oxalate, or citrate.
- The collection device cannot contain clot activators or serum separators.
- The sample should be immediately dispensed into the sample well of a cartridge.
- If a second measurement is required, a fresh sample must be obtained.

Note: Some experts recommend drawing and discarding a sample of at least 1 mL prior to drawing sample for coagulation testing.[5]

In-dwelling line

- Fluid drip through the line must be discontinued.
- Withdraw 2 mL of blood into a syringe and discard it.
- Withdraw the sample for testing into a fresh **plastic** syringe.
- The collection syringe **cannot contain anticoagulants** such as heparin, EDTA, oxalate, or citrate.
- The sample should be immediately dispensed into the sample well of a cartridge.
- If a second measurement is needed, draw a fresh sample.

Extracorporeal line

- Flush the extracorporeal blood access line by withdrawing 5 cc of blood into a syringe and discard the syringe.
- Withdraw the sample for testing into a fresh **plastic** syringe.
- The collection syringe **cannot contain anticoagulants** such as heparin, EDTA, oxalate, or citrate.
- The sample should be immediately dispensed into the sample well of a cartridge.
- If a second measurement is needed, draw a fresh sample.

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References

1. Hattersly, P. Activated coagulation time of whole blood. *Journal of the American Medical Association* 136:436-440, 1966.
2. NCCLS. *Method Comparison and Bias Estimation Using Patient Samples*; Approved Guideline. NCCLS document EP9-A (ISBN 1-56238-283-7). NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087, 1995.
3. P.J. Cornbleet and N. Gochman, "Incorrect Least-Squares Regression Coefficients in Method Comparison Analysis," *Clinical Chemistry* 25:3, 432 (1979).
4. Wang, JS; Lin, CY; Hung, WT; Thisted, RA; Carp, RB. *In vitro* effects of aprotinin on activated clotting time measured with different activators. *Journal of Thoracic Cardiovascular Surgery* 104(4):1135-40, 1992.
5. Corriveau, Donna: Fritsma, George (ed.): *Hemostasis and Thrombosis in the Clinical Laboratory*. Ed, J.B. Lippinncott Company, Philadelphia, 1988, pp 70-71.

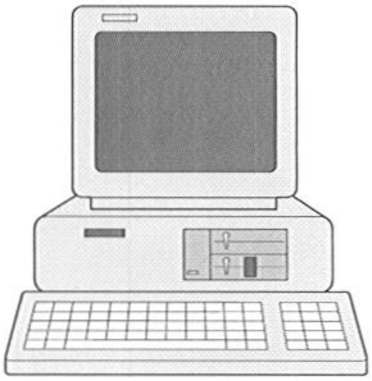
i-STAT is a registered trademark of i-STAT Corporation, East Windsor, NJ

Celite is a registered trademark of Celite Corporation, Santa Barbara, CA, for its diatomaceous earth products.

Hemochron is a registered trademark of International Technidyne Corporation, Edison, NJ

OPERATING PROCEDURES FOR THE CENTRAL DATA STATION

INTRODUCTION



The Central Data Station provides the primary information management capabilities for the i-STAT System. Using the Central Data Station software package, records from multiple analyzers can be viewed and printed. Identification numbers can be edited, and additional open fields are provided for each record to attach comments, and order numbers.*

i-STAT Central Data Station Main Screen

The main screen is displayed whenever the Central Data Station software is activated by its Icon from the Windows® operating system.

The ***Record Selection*** window (left side of screen) shows a summary list of patient and quality control records transmitted to the Central Data Station. Records are organized sequentially by date and time, so that most recent records are at the top of the list. The patient identification number that was input into the hand-held analyzer is also displayed along with the "sent" status. When a test record is selected for transmission, the Sent status indicates that the record is either in queue ("..."), is currently being transmitted ("—"),the transmission was attempted but failed (X), or that the transmission to another Central Data Station, LIS or HIS has been completed ("√").

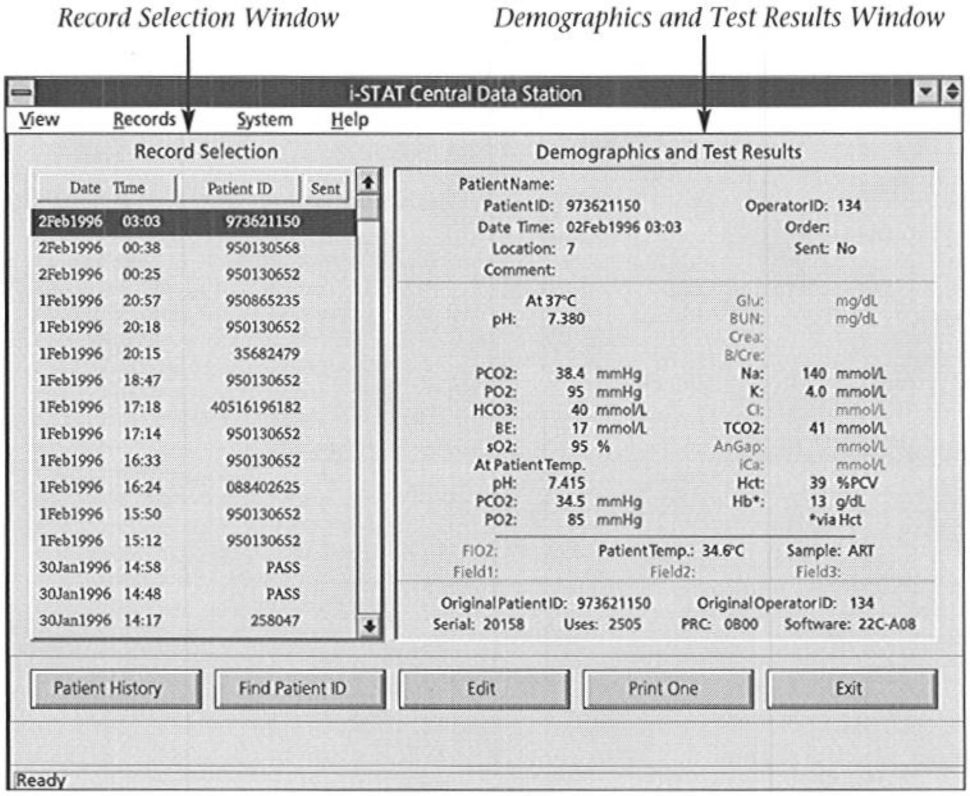
The ***Demographics and Test Results*** window (right side of screen) displays complete record contents. This includes test results, patient demographics and various other information fields. If a test parameter or information field was not appropriate to the specific cartridge used for testing, that test result field or information field is subdued in a light gray color and is empty of data. (Example—an EG6+ cartridge used in the example on the next page did not test for Glucose, Urea Nitrogen, Chloride, Anion Gap or Ionized Calcium so those fields are subdued to gray and are empty of results).

To view a specific record, the highlight band in the ***Record Selection*** window is placed on top of one of the entries in the list, and that record's contents are then displayed in the ***Demographics and Test Results*** window. Results can be selected in a number of ways:

- Clicking on an entry with the mouse
- Pressing the up or down arrow keys to move the highlight bar
- Pressing the Page Down or Page Up key to move the highlight bar through large sections of the list
- Pressing the Home key, which moves the selection bar to the newest record
- Pressing the End key, which moves the highlight bar to the oldest record

---

** An interactive tutorial for Microsoft Windows is available with the Windows operating system as the program called "Wintutor". (It can be accessed at C:\Windows\Wintutor.Exe) Use of this program is covered in the Windows documentation that was delivered with the computer system.*


Record Selection Window
Demographics and Test Results Window
i-STAT Central Data Station
View
Records
System
Help
Record Selection
Demographics and Test Results
Patient History
Find Patient ID
Edit
Print One
Exit
Ready

Date	Time	Patient ID	Sent
2Feb1996	03:03	973621150	
2Feb1996	00:38	950130568	
2Feb1996	00:25	950130652	
1Feb1996	20:57	950865235	
1Feb1996	20:18	950130652	
1Feb1996	20:15	35682479	
1Feb1996	18:47	950130652	
1Feb1996	17:18	40516196182	
1Feb1996	17:14	950130652	
1Feb1996	16:33	950130652	
1Feb1996	16:24	088402625	
1Feb1996	15:50	950130652	
1Feb1996	15:12	950130652	
30Jan1996	14:58	PASS	
30Jan1996	14:48	PASS	
30Jan1996	14:17	258047	

Patient Name:
Patient ID: 973621150 Operator ID: 134
Date Time: 02Feb1996 03:03 Order:
Location: 7 Sent: No
Comment:

At 37°C
pH: 7.380
PCO2: 38.4 mmHg
PO2: 95 mmHg
HCO3: 40 mmol/L
BE: 17 mmol/L
sO2: 95 %
At Patient Temp.
pH: 7.415
PCO2: 34.5 mmHg
PO2: 85 mmHg

Glu: mg/dL
BUN: mg/dL
Crea:
B/Cre:
Na: 140 mmol/L
K: 4.0 mmol/L
Cl: mmol/L
TCO2: 41 mmol/L
AnGap: mmol/L
iCa: mmol/L
Hct: 39 %PCV
Hb*: 13 g/dL
*via Hct

FIO2: Patient Temp.: 34.6°C Sample: ART
Field1: Field2: Field3:

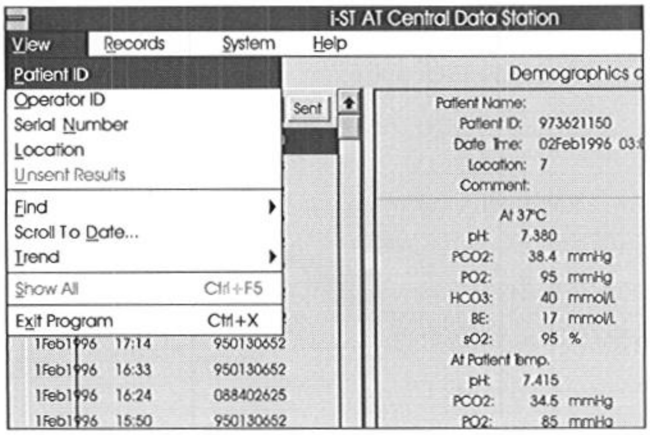
Original Patient ID: 973621150 Original Operator ID: 134
Serial: 20158 Uses: 2505 PRC: 0800 Software: 22C-A08

Using the Menu Bar

The menu bar across the top of the Central Data Station screen provides access to the Central Data Station's functions through a set of pull down menus. A pull down menu is opened by clicking on an item on the menu bar, or by pressing the ALT key and the underlined letter in an item's name. (Example: to access the View menu, hold down the ALT Key and press the V key) Functions in a menu are selected by: (1) clicking on the function name, (2) using the arrow keys to move the highlight to the function name and pressing ENTER, (3) or by pressing the key for the underlined letter in the function's name.

View Menu

To access the *View* menu, click on the word *View*. The *View* menu allows the operator to review results by specific selection criteria such as Patient ID, Operator ID and Unsent results (those results that have not been transmitted to another Central Data Station, LIS or HIS).


i-ST AT Central Data Station
View
Records
System
Help
Patient ID
Operator ID
Serial Number
Location
Unsent Results
Find
Scroll To Date...
Trend
Show All Ctrl+F5
Exit Program Ctrl+X
Sent
Demographics

1Feb1996 17:14 950130652
1Feb1996 16:33 950130652
1Feb1996 16:24 088402625
1Feb1996 15:50 950130652

Patient Name:
Patient ID: 973621150
Date Time: 02Feb1996 03:
Location: 7
Comment:
At 37°C
pH: 7.380
PCO2: 38.4 mmHg
PO2: 95 mmHg
HCO3: 40 mmol/L
BE: 17 mmol/L
sO2: 95 %
At Patient Temp.
pH: 7.415
PCO2: 34.5 mmHg
PO2: 85 mmHg

Patient ID/Operator ID

Clicking on *Patient ID/Operator ID* allows the user to limit the ***Record Selection*** window to show only those records in the last ±32 days where the Patient ID/Operator ID is the same as the highlighted record .

Serial Number/Location

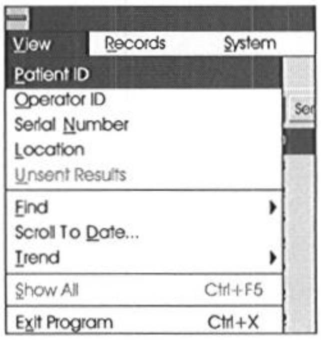
The user is able to limit the ***Record Selection*** window to only those records generated by a specific analyzer/from a specific location by highlighting one of its records in the ***Record Selection*** window, and then clicking on Serial Number/Location from the *View* Menu.

Unsent Results

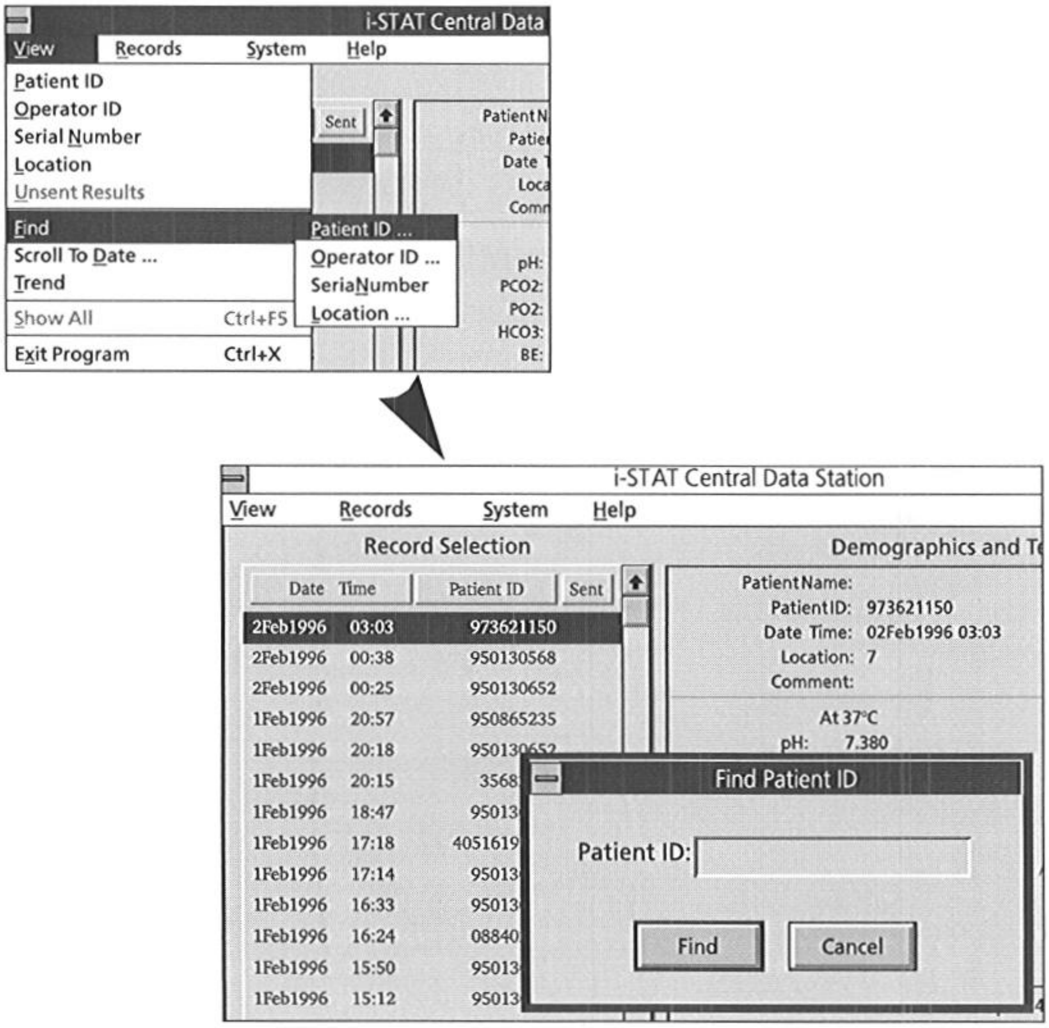
Clicking on *Unsent Results* allows the user to limit the ***Record Selection*** window to only those records in the last ±32 days that have not been sent on to another Central Data Station, LIS or HIS. This option is available only if the Central Data Station has been configured to send records to another Central Data Station, LIS or HIS.

Find

Clicking on *Find* allows the operator to input a Patient ID, Operator ID, Serial Number or Location. The ***Record Selection*** window will show only those records in the last ±32 days where the specified selection occurs. The most recent result will be highlighted.


View
Records
System
Patient ID
Operator ID
Serial Number
Location
Unsent Results
Find
Scroll To Date...
Trend
Show All Ctrl+F5
Exit Program Ctrl+X

View Menu


i-STAT Central Data
View
Records
System
Help
Patient ID
Operator ID
Serial Number
Location
Unsent Results
Find
Scroll To Date ...
Trend
Show All Ctrl+F5
Exit Program Ctrl+X
Patient ID ...
Operator ID ...
SeriaNumber
Location ...
Sent
PatientN
Patie
Date T
Loca
Comn
pH:
PCO2:
PO2:
HCO3:
BE:
i-STAT Central Data Station
View
Records
System
Help
Record Selection
Demographics and T
Find Patient ID
Find
Cancel

Date	Time	Patient ID	Sent
2Feb1996	03:03	973621150	
2Feb1996	00:38	950130568	
2Feb1996	00:25	950130652	
1Feb1996	20:57	950865235	
1Feb1996	20:18	95013	
1Feb1996	20:15	3568	
1Feb1996	18:47	95013	
1Feb1996	17:18	4051619	
1Feb1996	17:14	95013	
1Feb1996	16:33	95013	
1Feb1996	16:24	08840	
1Feb1996	15:50	95013	
1Feb1996	15:12	95013	

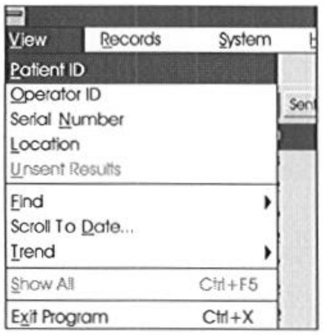
PatientName:
PatientID: 973621150
Date Time: 02Feb1996 03:03
Location: 7
Comment:

At 37°C
pH: 7.380

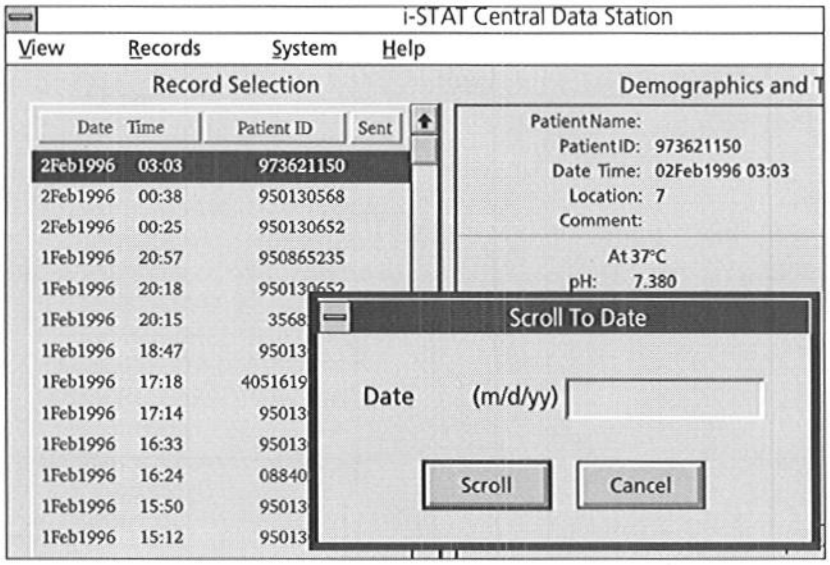
Patient ID:

Scroll to Date

Clicking on *Scroll to Date* allows the operator to input a specific date, and then click on the *Scroll* button to move the highlight bar to the newest result for the given date. If results do not exist for the entered date, the nearest date to the specified date is selected and highlighted.


View
Records
System
Patient ID
Operator ID
Serial Number
Location
Unsent Results
Find
Scroll To Date...
Trend
Show All Ctrl+F5
Exit Program Ctrl+X
Sen

View Menu


i-STAT Central Data Station
View
Records
System
Help
Record Selection
Demographics and T
Date Time
Patient ID
Sent
Scroll To Date
Scroll
Cancel

2Feb1996 03:03 973621150
2Feb1996 00:38 950130568
2Feb1996 00:25 950130652
1Feb1996 20:57 950865235
1Feb1996 20:18 95013065
1Feb1996 20:15 3568
1Feb1996 18:47 95013
1Feb1996 17:18 4051619
1Feb1996 17:14 95013
1Feb1996 16:33 95013
1Feb1996 16:24 08840
1Feb1996 15:50 95013
1Feb1996 15:12 95013

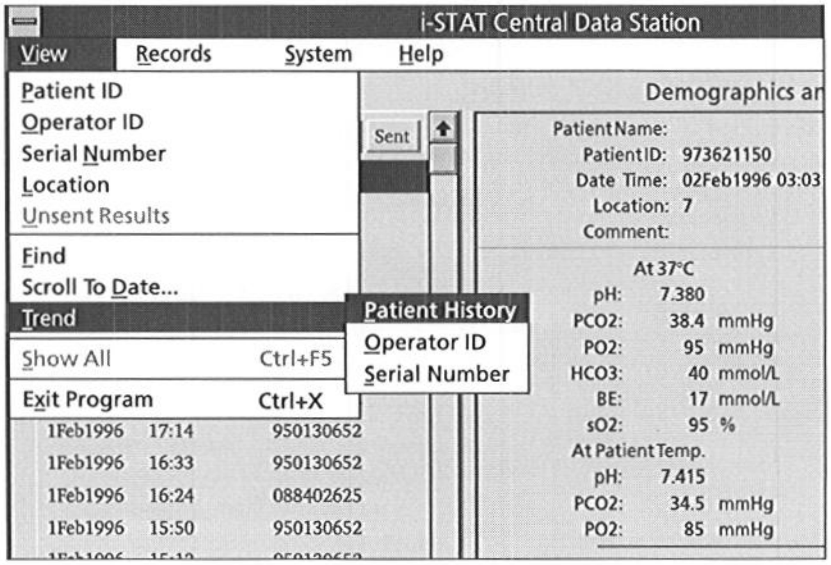
Patient Name:
Patient ID: 973621150
Date Time: 02Feb1996 03:03
Location: 7
Comment:
At 37°C
pH: 7.380

Date (m/d/yy)

Trend

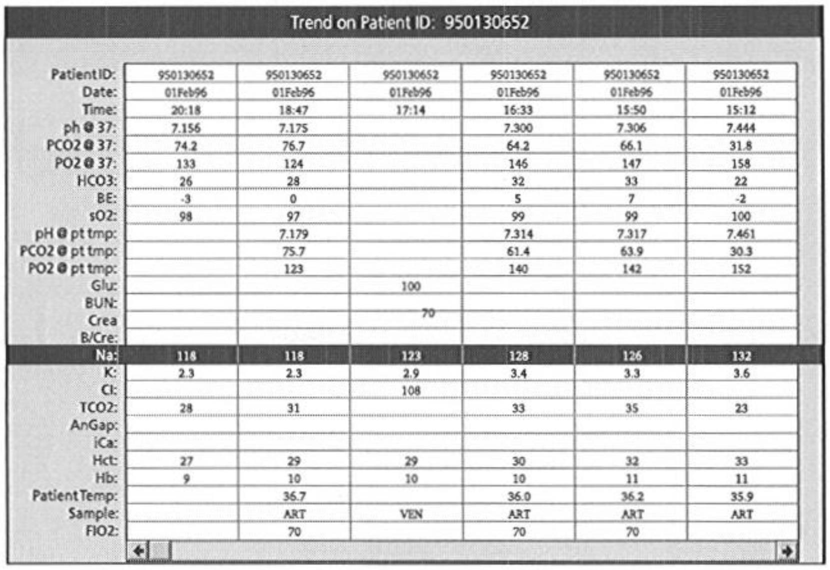
By highlighting a specific record in the *Record Selection* window, and then clicking on *Trend*, an operator is able to display a tabular summary of results for the selected Patient ID, Operator ID, or analyzer serial number. The first column corresponds to the highlighted record, and the remaining columns (left to right) display earlier records. Records shown may be from up to 30 days prior or 25 total records, which ever is reached first.

If more than one record is present on the Trend display, a graphing option is available. Otherwise, the Graph button appears in light gray and is inactive.


i-STAT Central Data Station
View
Records
System
Help
Patient ID
Operator ID
Serial Number
Location
Unsent Results
Find
Scroll To Date...
Trend
Show All Ctrl+F5
Exit Program Ctrl+X
Patient History
Operator ID
Serial Number
Sent
Demographics ar

1Feb1996 17:14 950130652
1Feb1996 16:33 950130652
1Feb1996 16:24 088402625
1Feb1996 15:50 950130652

Patient Name:
Patient ID: 973621150
Date Time: 02Feb1996 03:03
Location: 7
Comment:
At 37°C
pH: 7.380
PCO2: 38.4 mmHg
PO2: 95 mmHg
HCO3: 40 mmol/L
BE: 17 mmol/L
sO2: 95 %
At Patient Temp.
pH: 7.415
PCO2: 34.5 mmHg
PO2: 85 mmHg



Trend on Patient ID: 950130652

Patient ID:	950130652	950130652	950130652	950130652	950130652	950130652
Date:	01Feb96	01Feb96	01Feb96	01Feb96	01Feb96	01Feb96
Time:	20:18	18:47	17:14	16:33	15:50	15:12
ph @ 37:	7.156	7.175		7.300	7.306	7.444
PCO2 @ 37:	74.2	76.7		64.2	66.1	31.8
PO2 @ 37:	133	124		146	147	158
HCO3:	26	28		32	33	22
BE:	-3	0		5	7	-2
sO2:	98	97		99	99	100
pH @ pt tmp:		7.179		7.314	7.317	7.461
PCO2 @ pt tmp:		75.7		61.4	63.9	30.3
PO2 @ pt tmp:		123		140	142	152
Glu:			100			
BUN:			70			
Crea						
B/Cre:						
Na:	118	118	123	128	126	132
K:	2.3	2.3	2.9	3.4	3.3	3.6
Cl:			108			
TCO2:	28	31		33	35	23
AnGap:						
iCa:						
Hct:	27	29	29	30	32	33
Hb:	9	10	10	10	11	11
Patient Temp:		36.7		36.0	36.2	35.9
Sample:		ART	VEN	ART	ART	ART
FIO2:		70		70	70	

Show All

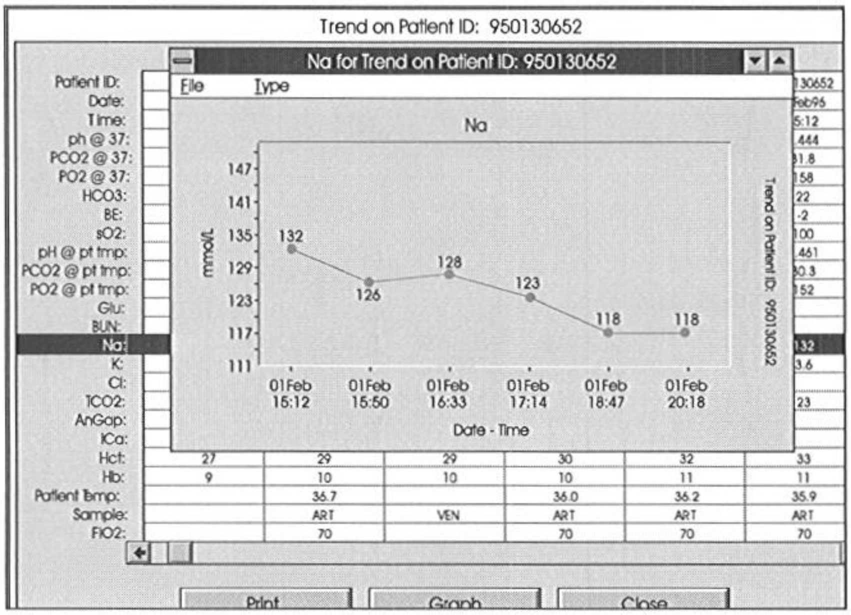
Clicking on *Show All* removes any limits that have been placed on the contents of the ***Record Selection*** window, allowing all records to be accessed. If no limits are in place, *Show All* appears in light gray and is inactive.

Exit Program

The Central Data Station program will shutdown by clicking on *Exit Program*.

Graph Option

Clicking on the Graph option from the Trend display gives a graphical representation of a result trend. Only one test result from the patient record may be shown graphically at one time. To graph a trend, click on a single result row to select it, and then click on the Graph button.



Trend on Patient ID: 950130652

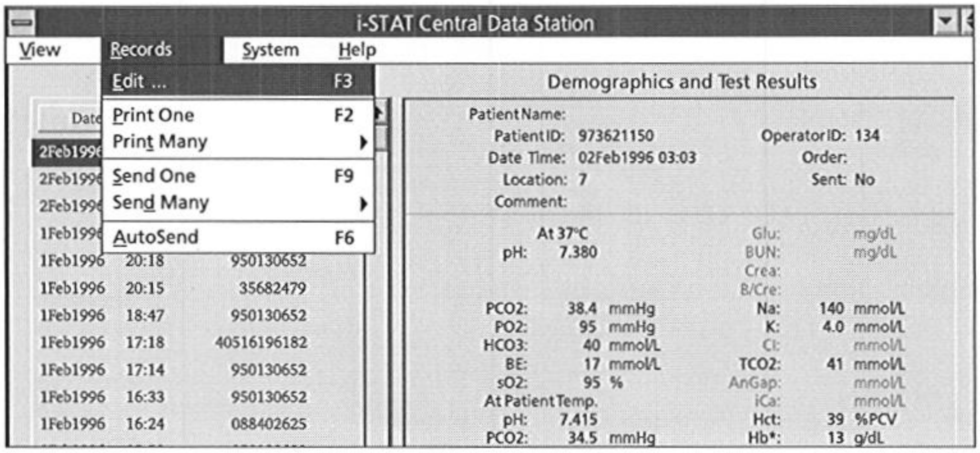
Na for Trend on Patient ID: 950130652

Hct:	27	29	29	30	32	33
Hb:	9	10	10	10	11	11
Patient Temp:		36.7		36.0	36.2	35.9
Sample:		ART	VEN	ART	ART	ART
FIO2:		70		70	70	70

File
Type
Na
mmol/L
147
141
135
129
123
117
111
132
126
128
123
118
118
01Feb 15:12
01Feb 15:50
01Feb 16:33
01Feb 17:14
01Feb 18:47
01Feb 20:18
Date - Time
Trend on Patient ID: 950130652
Patient ID:
Date:
Time:
ph @ 37:
PCO2 @ 37:
PO2 @ 37:
HCO3:
BE:
sO2:
pH @ pt tmp:
PCO2 @ pt tmp:
PO2 @ pt tmp:
Glu:
BUN:
Na:
K:
Cl:
TCO2:
AnGap:
ICa:
130652
Feb96
5:12
.444
31.8
158
22
-2
100
.461
30.3
152
132
3.6
23
Print
Graph
Close

Records Menu

The *Records* menu allows the user to edit, print or transmit patient records. To access the Records menu, click on the word *Records*.


i-STAT Central Data Station
View
Records
System
Help
Edit ... F3
Print One F2
Print Many
Send One F9
Send Many
AutoSend F6
Date
Demographics and Test Results

2Feb199		
2Feb199		
2Feb199		
1Feb199		
1Feb1996	20:18	950130652
1Feb1996	20:15	35682479
1Feb1996	18:47	950130652
1Feb1996	17:18	40516196182
1Feb1996	17:14	950130652
1Feb1996	16:33	950130652
1Feb1996	16:24	088402625

Patient Name:
Patient ID: 973621150
Operator ID: 134
Date Time: 02Feb1996 03:03
Order:
Location: 7
Sent: No
Comment:

At 37°C
pH: 7.380
PCO2: 38.4 mmHg
PO2: 95 mmHg
HCO3: 40 mmol/L
BE: 17 mmol/L
sO2: 95 %
At Patient Temp.
pH: 7.415
PCO2: 34.5 mmHg

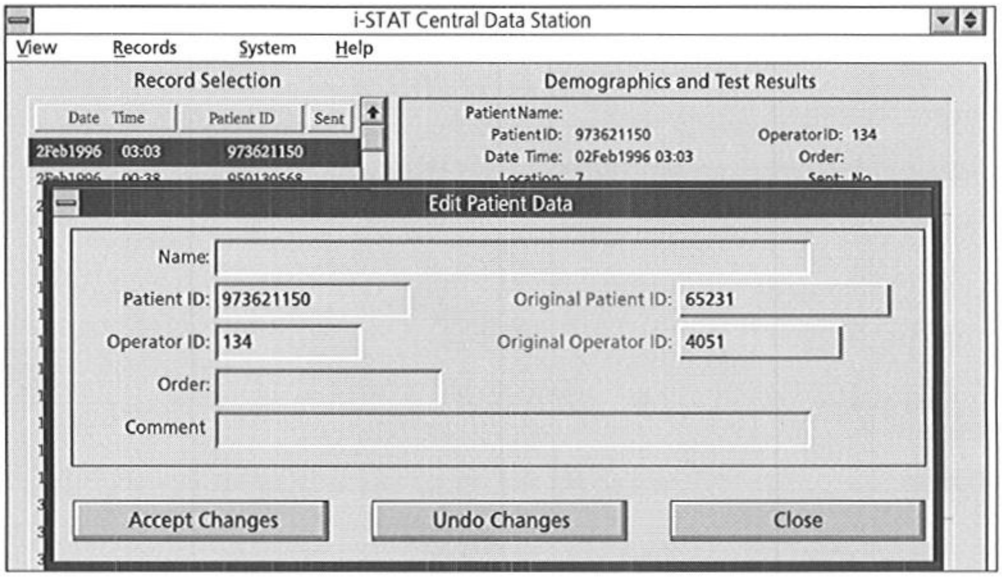
Glu: mg/dL
BUN: mg/dL
Crea:
B/Cre:
Na: 140 mmol/L
K: 4.0 mmol/L
Cl: mmol/L
TCO2: 41 mmol/L
AnGap: mmol/L
iCa: mmol/L
Hct: 39 %PCV
Hb*: 13 g/dL

Edit

NOTE:

Only the comment field can be edited within an electronic simulator record or once a record has been sent to the LIS/HIS or another Central Data Station.

By highlighting a specific record in the ***Record Selection*** window, and then clicking on *Edit* from the *Records* menu, an operator can edit the Patient Name, Patient ID, Operator ID, Order and Comment Fields of that record on the ***Demographics and Test Results*** window. By clicking on a field with the mouse, or by pressing the Tab key to move from one field to the next, place the cursor in the desired field and input or correct the information. When all the desired information has been edited, click on the *Accept Changes* button to update the record. *Undo Changes* will reset the fields to the original values. The *Close* button is used to exit the ***Demographics and Test Results*** window without updating the displayed information.


i-STAT Central Data Station
View
Records
System
Help
Record Selection
Date Time
Patient ID
Sent
Demographics and Test Results
Edit Patient Data
Accept Changes
Undo Changes
Close

2Feb1996 03:03 973621150

Patient Name:
Patient ID: 973621150
Operator ID: 134
Date Time: 02Feb1996 03:03
Order:

Name:
Patient ID: 973621150
Original Patient ID: 65231
Operator ID: 134
Original Operator ID: 4051
Order:
Comment

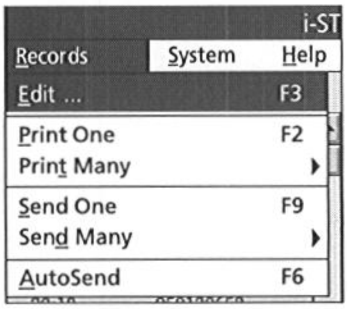
124

Print One

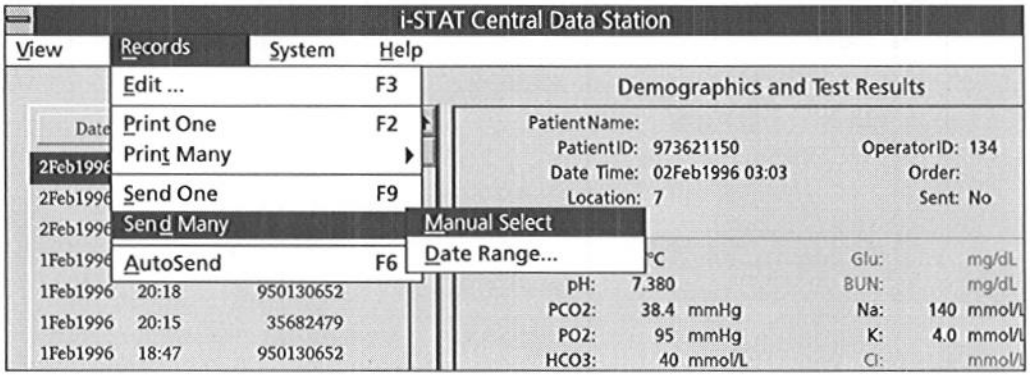
The user is able to print a copy of the selected record to a line printer that is connected to the Central Data Station by highlighting a specific record in the ***Record Selection*** window, and then clicking on *Print One* from the Records menu.

Print Many

The user is able to print multiple records to a line printer that is connected to the Central Data Station by clicking on *Print Many* from the Records menu. Using Manual Select, multiple records in the ***Record Selection*** window can be highlighted and then printed one per page or in tabular form with up to 8 records per page. Using *Selection Window Contents,* all 16 records showing in the ***Record Selection*** window will be printed in tabular form. Using *Date Range*, records from a specific date or range of dates are printed in tabular form, with up to 8 records per page.


i-ST
Records
System
Help
Edit ... F3
Print One F2
Print Many
Send One F9
Send Many
AutoSend F6

Records Menu


i-STAT Central Data Station
View
Records
System
Help
Edit ... F3
Print One F2
Print Many
Send One F9
Send Many
AutoSend F6
Manual Select
Date Range...
Demographics and Test Results

Date

2Feb1996

2Feb1996

2Feb1996

1Feb1996

1Feb1996 20:18 950130652

1Feb1996 20:15 35682479

1Feb1996 18:47 950130652

PatientName:
PatientID: 973621150
Date Time: 02Feb1996 03:03
Location: 7
OperatorID: 134
Order:
Sent: No

°C
pH: 7.380
PCO2: 38.4 mmHg
PO2: 95 mmHg
HCO3: 40 mmol/L
Glu: mg/dL
BUN: mg/dL
Na: 140 mmol/L
K: 4.0 mmol/L
Cl: mmol/L

Send One, Send Many

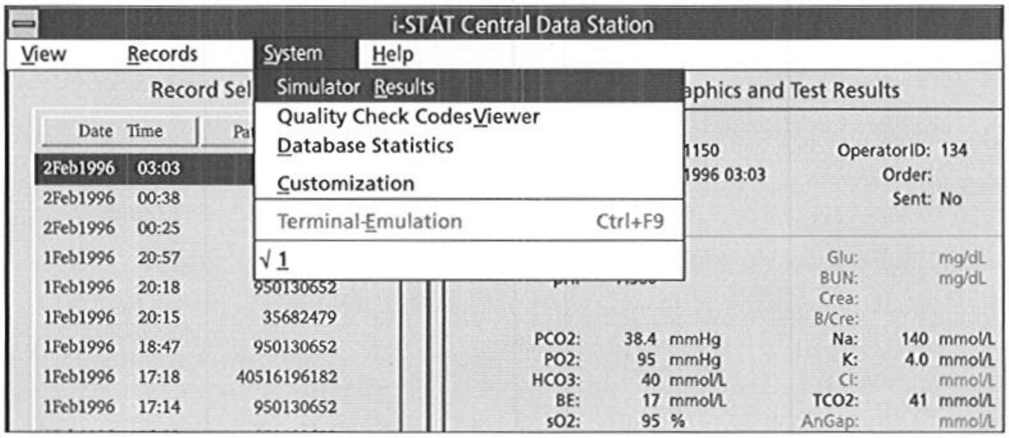
The *Send* functions are only active if the Central Data Station is interfaced to a Laboratory Information System, Hospital Information System or another Central Data Station. The user is able to queue the specific record for transmission to the remote information system by highlighting a specific record in the ***Record Selection*** window, and then clicking on *Send One* from the Records menu. When the user clicks on *Send Many,* multiple records in the ***Record Selection*** window can be highlighted (manual select) and then queued for transmission to the remote information system or records from a specific date or range of dates can be selected (Date Range).

AutoSend

Each time the Central Data Station application is started the *Auto Send* function is enabled or disabled depending on the default settings in the Configuration Screen. A check mark next to *AutoSend* in the Records menu indicates that this function is enabled. To temporarily change this state during a session, click on *AutoSend* (this does not alter the default settings of the configuration).

System Menu

To access the System menu, click on the word *System*.


i-STAT Central Data Station
View
Records
System
Help
Record Sel
Simulator Results
Quality Check Codes Viewer
Database Statistics
Customization
Terminal-Emulation Ctrl+F9
√ 1
aphics and Test Results
Date Time
Pa

2Feb1996 03:03
2Feb1996 00:38
2Feb1996 00:25
1Feb1996 20:57
1Feb1996 20:18 950130652
1Feb1996 20:15 35682479
1Feb1996 18:47 950130652
1Feb1996 17:18 40516196182
1Feb1996 17:14 950130652

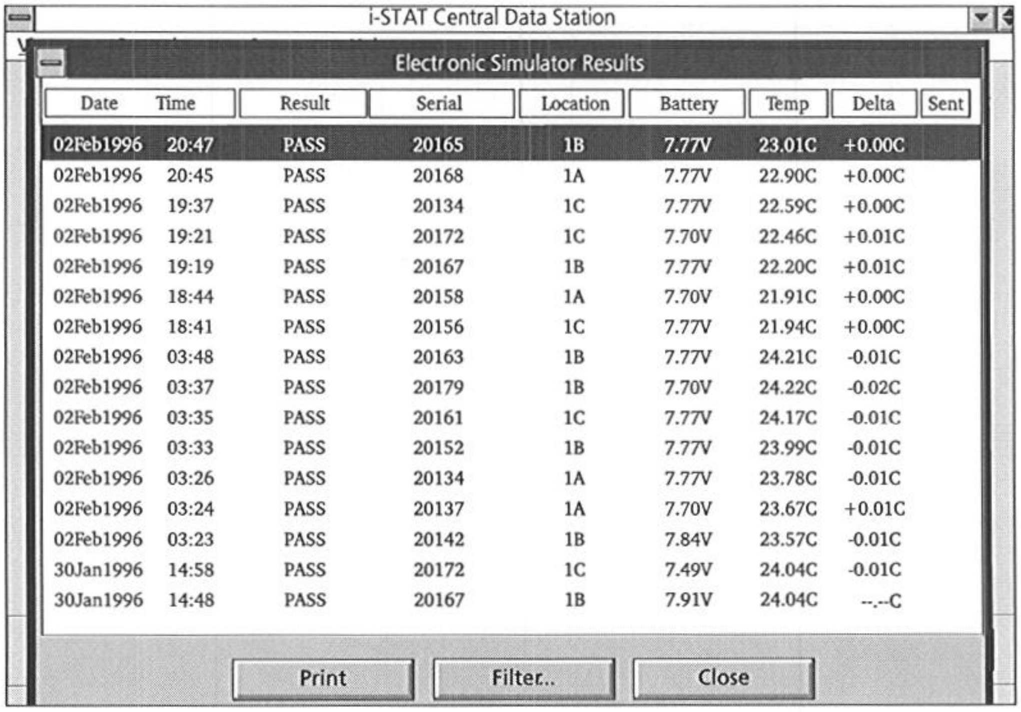
1150
1996 03:03
OperatorID: 134
Order:
Sent: No

PCO2: 38.4 mmHg
PO2: 95 mmHg
HCO3: 40 mmol/L
BE: 17 mmol/L
sO2: 95 %

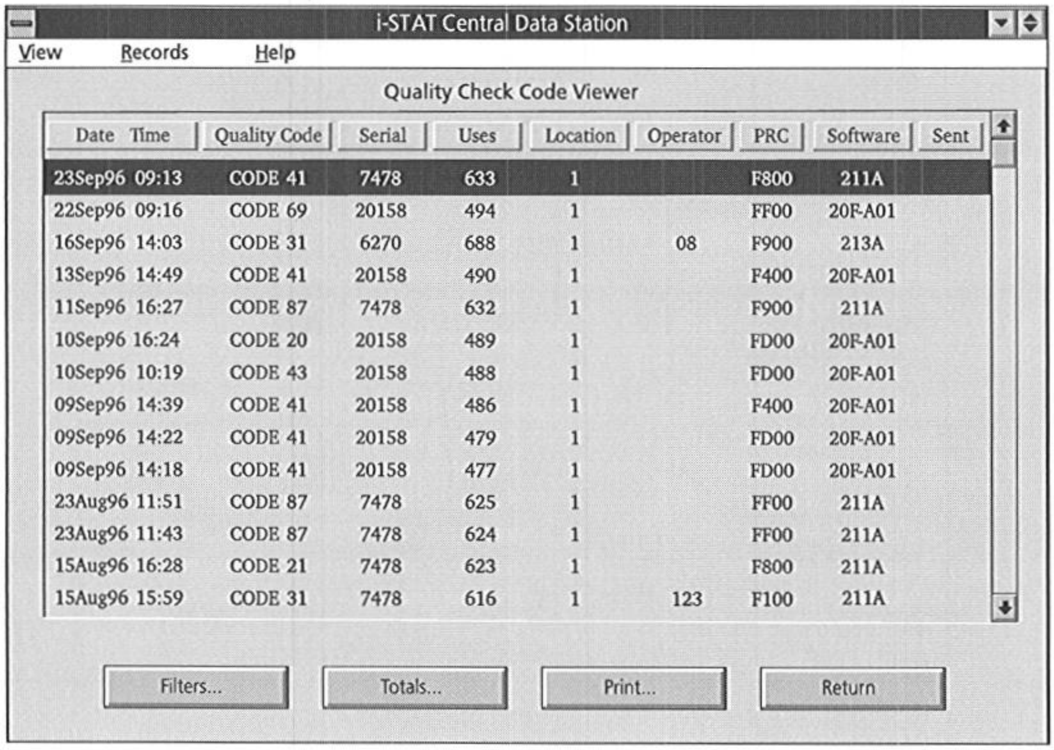
Glu: mg/dL
BUN: mg/dL
Crea:
B/Cre:
Na: 140 mmol/L
K: 4.0 mmol/L
Cl: mmol/L
TCO2: 41 mmol/L
AnGap: mmol/L

Simulator Results

To view Electronic Simulator results in a single display window, click on *Simulator Results* from the *System* menu. Results can be printed by date range or can be filtered by Serial Number or Location and then printed.


i-STAT Central Data Station
Electronic Simulator Results
Print
Filter..
Close

Date	Time	Result	Serial	Location	Battery	Temp	Delta	Sent
02Feb1996	20:47	PASS	20165	1B	7.77V	23.01C	+0.00C	
02Feb1996	20:45	PASS	20168	1A	7.77V	22.90C	+0.00C	
02Feb1996	19:37	PASS	20134	1C	7.77V	22.59C	+0.00C	
02Feb1996	19:21	PASS	20172	1C	7.70V	22.46C	+0.01C	
02Feb1996	19:19	PASS	20167	1B	7.77V	22.20C	+0.01C	
02Feb1996	18:44	PASS	20158	1A	7.70V	21.91C	+0.00C	
02Feb1996	18:41	PASS	20156	1C	7.77V	21.94C	+0.00C	
02Feb1996	03:48	PASS	20163	1B	7.77V	24.21C	-0.01C	
02Feb1996	03:37	PASS	20179	1B	7.70V	24.22C	-0.02C	
02Feb1996	03:35	PASS	20161	1C	7.77V	24.17C	-0.01C	
02Feb1996	03:33	PASS	20152	1B	7.77V	23.99C	-0.01C	
02Feb1996	03:26	PASS	20134	1A	7.77V	23.78C	-0.01C	
02Feb1996	03:24	PASS	20137	1A	7.70V	23.67C	+0.01C	
02Feb1996	03:23	PASS	20142	1B	7.84V	23.57C	-0.01C	
30Jan1996	14:58	PASS	20172	1C	7.49V	24.04C	-0.01C	
30Jan1996	14:48	PASS	20167	1B	7.91V	24.04C	--.--C	



Quality Check Code Viewer

Date Time	Quality Code	Serial	Uses	Location	Operator	PRC	Software	Sent
23Sep96 09:13	CODE 41	7478	633	1		F800	211A	
22Sep96 09:16	CODE 69	20158	494	1		FF00	20F-A01	
16Sep96 14:03	CODE 31	6270	688	1	08	F900	213A	
13Sep96 14:49	CODE 41	20158	490	1		F400	20F-A01	
11Sep96 16:27	CODE 87	7478	632	1		F900	211A	
10Sep96 16:24	CODE 20	20158	489	1		FD00	20F-A01	
10Sep96 10:19	CODE 43	20158	488	1		FD00	20F-A01	
09Sep96 14:39	CODE 41	20158	486	1		F400	20F-A01	
09Sep96 14:22	CODE 41	20158	479	1		FD00	20F-A01	
09Sep96 14:18	CODE 41	20158	477	1		FD00	20F-A01	
23Aug96 11:51	CODE 87	7478	625	1		FF00	211A	
23Aug96 11:43	CODE 87	7478	624	1		FF00	211A	
15Aug96 16:28	CODE 21	7478	623	1		F800	211A	
15Aug96 15:59	CODE 31	7478	616	1	123	F100	211A	

Quality Check Codes Viewer

Clicking on *Quality Check Codes Viewer* opens a window which displays a listing of analyses where the analyzer detected the failure of one of the i-STAT quality checks. The results can be filtered by Location, Serial Number, Operator ID or Unsent codes. Totals can be computed for all data or by date range, and data can be sent to a printer or a file by date range. For further information about the quality check codes, see i-STAT Technical Bulletin "ANALYZER CODED MESSAGES".

Database Statistics ...

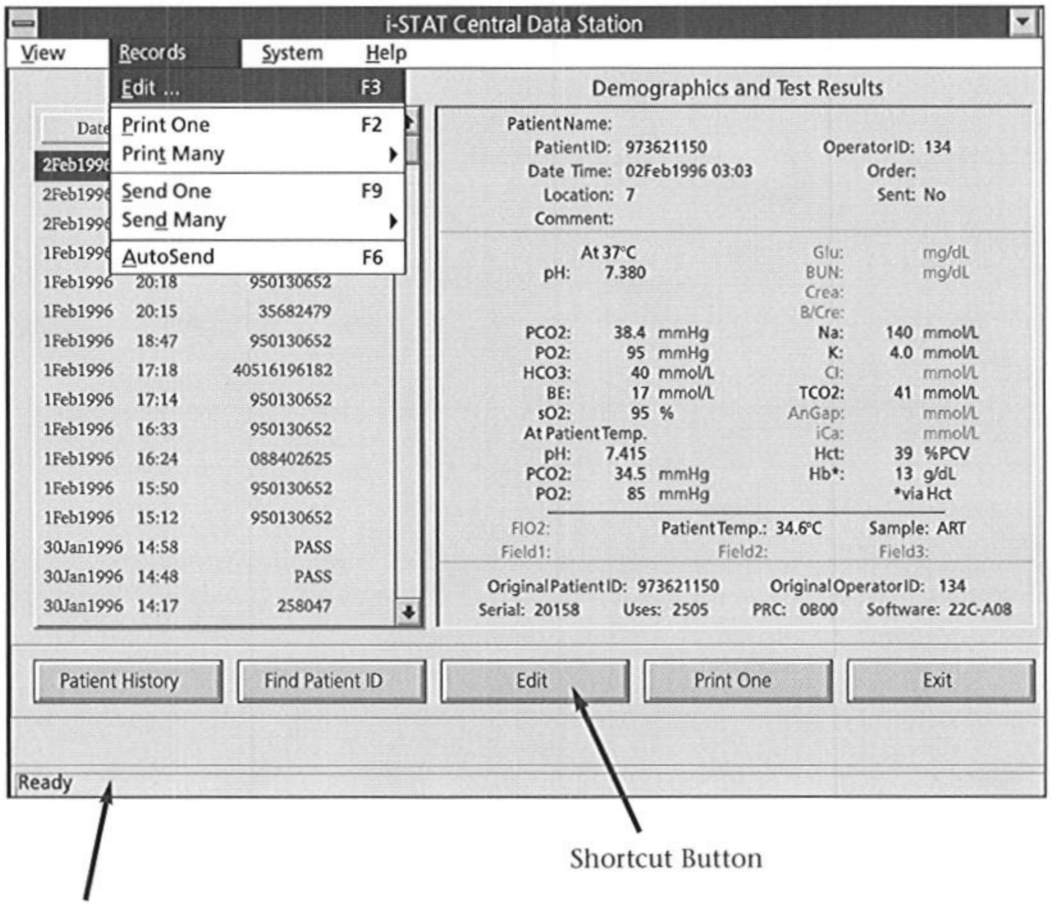
Customization

Terminal Emulation

Terminal Emulation is only enabled when an AME interface is present. The user is able to use the Central Data Station as an LIS terminal by clicking on *Terminal Emulation* from the *System* Menu.

Help Menu

The *Help* menu displays the i-STAT Technical Support telephone number and confirms the current version of Central Data Station software being run. Additional on-line help utilities will be added in this area of the menu in future software releases.


i-STAT Central Data Station
View
Records
System
Help
Edit ... F3
Print One F2
Print Many
Send One F9
Send Many
AutoSend F6
Demographics and Test Results
Patient History
Find Patient ID
Edit
Print One
Exit
Ready

Date		
2Feb199		
2Feb199		
2Feb199		
1Feb199		
1Feb1996	20:18	950130652
1Feb1996	20:15	35682479
1Feb1996	18:47	950130652
1Feb1996	17:18	40516196182
1Feb1996	17:14	950130652
1Feb1996	16:33	950130652
1Feb1996	16:24	088402625
1Feb1996	15:50	950130652
1Feb1996	15:12	950130652
30Jan1996	14:58	PASS
30Jan1996	14:48	PASS
30Jan1996	14:17	258047

PatientName:
PatientID: 973621150 OperatorID: 134
Date Time: 02Feb1996 03:03 Order:
Location: 7 Sent: No
Comment:

At 37°C			Glu:		mg/dL
pH:	7.380		BUN:		mg/dL
			Crea:		
			B/Cre:		
PCO2:	38.4	mmHg	Na:	140	mmol/L
PO2:	95	mmHg	K:	4.0	mmol/L
HCO3:	40	mmol/L	Cl:		mmol/L
BE:	17	mmol/L	TCO2:	41	mmol/L
sO2:	95	%	AnGap:		mmol/L
At Patient Temp.			iCa:		mmol/L
pH:	7.415		Hct:	39	%PCV
PCO2:	34.5	mmHg	Hb*:	13	g/dL
PO2:	85	mmHg			*via Hct

FIO2: Patient Temp.: 34.6°C Sample: ART
Field1: Field2: Field3:
Original Patient ID: 973621150 Original Operator ID: 134
Serial: 20158 Uses: 2505 PRC: 0B00 Software: 22C-A08

Shortcut Button

Status Bar

Shortcut Buttons

A variety of shortcut buttons appear at the bottom of various windows. These buttons allow quick access to various system functions and eliminate the need to access certain frequently used functions though the menu structure.

Status Bar

The status bar appears at the bottom of each window and offers a brief description of the function performed by the currently highlighted menu item or the currently depressed shortcut button.

INSTALLATION AND TECHNICAL INFORMATION

The computer supplied by i-STAT is intended to be used as a Central Data Station dedicated to the collection, review and reduction of data transmitted from i-STAT analyzers. All necessary software packages are installed by i-STAT. Only those programs either supplied or approved by i-STAT should be installed on this computer. Unauthorized programs may cause corruption of data. Updated Central Data Station software along with an installation procedure will be provided whenever new programs are developed. The software version is found when clicking on "About.." in the *Help* pull-down menu.

The computer is shipped with the manufacturer's manuals. Installation instructions pertinent to the i-STAT System are summarized below.

Connecting the Printer

Insert the printer's cable connector into the computer's printer port on the back side. Tighten the screws that fasten the cable connector to the computer. Insert the other end into the printer's parallel port, and use the clips on the printer port to secure the connector. See the printer manual for instructions on installing ink cartridge, paper and programming.

Connecting the IR Link

To connect an IR Link or Interface to a Central Data Station, insert one end of the cable plug into the cradle and the other in to one of the four or eight ports (RJ-45-8, similar to modular phone jack) on the back of the Central Data Station.

Connecting to Other Central Data Stations

Consult your local representative.

Connecting LIS Cable

Contact the Laboratory Information System operator.

Turning the Computer On and Off

The computer and printer should be left on. When moving the system, exit all applications, turn the computer off first (before the printer) and back on last (after the printer). Remove and replace cables with the components off.

Turn the computer off first (before the printer) and on last (after the printer). Remove and replace cables with the components off.

Caution: *Avoid turning the computer off while the disk drive indicator lights are flashing because data may be corrupted. Always wait at least 5 seconds between turning the computer off and turning it back on again. When the computer is turned back on, it will go through a start-up sequence and display the data collection screen.* ***Avoid turning off before exiting the CDS software.***

Updating the Software

Whenever new tests or features become available, a floppy disk set will be provided to update the Central Data Station. A Product Update will describe the new features and note whether or not an LIS or HIS interface must be updated.

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CONFIGURATION & DATA BACKUP

i-STAT Central Data Station Configuration Screen

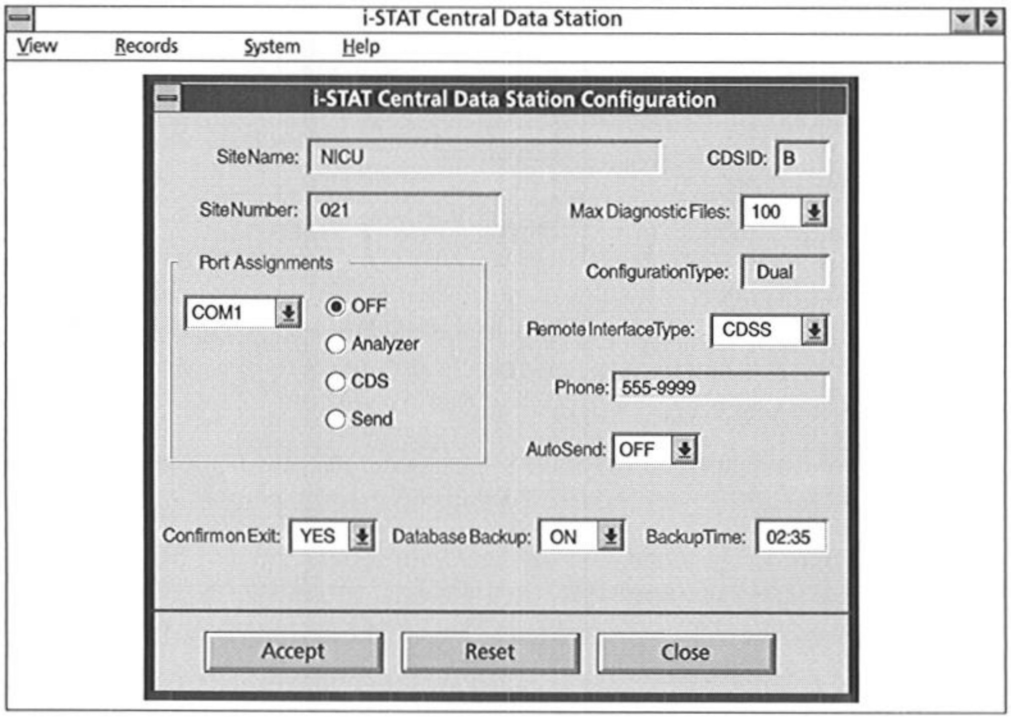
The Central Data Station must be configured properly to communicate with printers and its other components. Additionally, the name of the organization and a site number can be assigned, and will appear on printed records.

To access the Configuration Screen, the Central Data Station application must not be active. Click on the Program Manager's "File" menu, then click "Run". Enter "ISTATCDS CONFIG" in the entry field when prompted, and click the "OK" button.

When the Configuration Screen appears, use the tab key to advance to the various fields. The information in each field may be edited, and is explained below. Once information is correct in all fields, click on the "Accept" button to save the information and start the Central Data Station application. The "Reset" button will clear any changes and restore the fields to the original information. "Close" will ignore changes and start the Central Data Station application.

Site Name	A site name and address up to 60 characters can be entered in this field. The default name is i-STAT.
Site Number	Up to 20 digits can be entered, and this number is included in the header record of ASTM transmissions to a Laboratory Information System or other host. The default number is 1.
CDS ID	A letter is entered to identify the Central Data Station that originally received the test record from the analyzer via an IR Link. This is relevant if your organization uses several Central Data Stations.
Max Diagnostic Files	The default number is set to 100, and is changed at the request of your local technical representative for troubleshooting purposes.
Configuration Type	The default is "Dual", to indicate that two multiport serial cards are installed in the Central Data Station. Contact your local representative if it becomes necessary to alter this setting.
Port Assignments	COM1 and COM4 are used to send or receive records from a remote information system (LIS, HIS, or another Central Data Station) and for the internal modem. The default assignments are OFF. COM 2, COM 3 and COM 5 through COM 9 are used for receiving data from Analyzers via IR links. The assignment of a highlighted port is indicated with the button selections shown. They may be changed by pointing the screen arrow to another button and clicking the mouse once.
Remote Interface	OFF disables serial transmission to a remote computer system. ASTM enables the ASTM format transmission through the port (COM 1 or COM 4) designated with SEND. AME enables the i-STAT Automated Manual Entry Interface through the port (COM1 or COM4) designated with SEND. CDSS enables transmission to another Central Data Station through the port (COM1 or COM4) designated with SEND.

30


i-STAT Central Data Station
View
Records
System
Help
i-STAT Central Data Station Configuration
Accept
Reset
Close

SiteName: NICU

CDSID: B

SiteNumber: 021

Max Diagnostic Files: 100

Port Assignments

COM1

● OFF

○ Analyzer

○ CDS

○ Send

ConfigurationType: Dual

Remote InterfaceType: CDSS

Phone: 555-9999

AutoSend: OFF

Confirm on Exit: YES

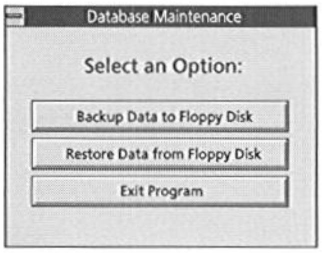
Database Backup: ON

BackupTime: 02:35

Phone	Remote interface connections using the internal modem are made to the designated number entered here. In most cases, COM4 should be the port designated as SEND.
AutoSend	ON enables the automatic sending of new results through the remote interface. OFF is the default entry.
Confirm Exit	This field is used to prevent the accidental shutdown of the *on* Central Data Station application by prompting users to confirm a shutdown request. YES enables this function.
Database Backup	Daily automatic backups of the Central Data Station's database are made when this field is set to ON. Each backup replaces the previous one.
Backup Time	If the Database Backup field is set to ON, the time the backup occurs is indicated in this field.

Database Maintenance

Like all database programs, the i-STAT Central Data Station application will perform its functions faster when not bogged down with an overloaded data file. A regular protocol for backing up and removing data from the system will insure the ability to recover data in the event of a computer failure, and keep the system at an optimal performance level.



Data Backup

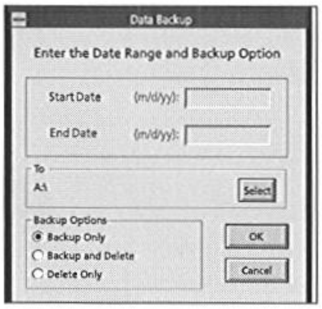
i-STAT recommends making regular backup copies of data collected on the Central Data Station computer. This may be on a daily, weekly, or monthly basis. The facility must decide how much data it is willing to lose in case of a hard-disk crash. Mean Time Between Failures (MTBF) for typical hard disks is 20,000 to 50,000 hours (two to five years). Hard disk failure may make all data on the disk inaccessible.

If all results are regularly transferred to a Laboratory Information System and are not used for any other purposes, backup copies may be unnecessary.

For users interested in archival storage of Central Data Station data, an easy to use utility program is provided to back up data, delete data from the system, and restore backup data to the system. The i-STAT Central Data Station stores its data in a relational database in a proprietary format, so using the provided utility program is required for necessary backup functions.

To start the utility, double click on the "Data Backup and Restore" icon shown when using the Program Manager. After initializing this application, the Database Maintenance window will appear. Choose the desired function by clicking on the appropriate screen button.

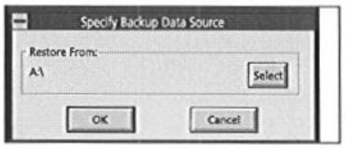
Backup Data to Floppy Disk



To: A:\

● Backup Only

At the Data Backup window, a specific date range of data can be indicated for Backup, Backup and Delete, or Delete Only. The *Backup Only* option will create a backup of the specified data on the specified drive and leave the data intact in the system database. The *Backup and Delete* option will remove each result from the system database after the backup has been completed on the specified drive. The *Delete Only* option removes the specified results from the system database without backing them up. Use this option only if the data is absolutely not needed, or has been previously backed up. Data that is not needed on a regular basis should be removed periodically to maintain system responsiveness.



Restore From: A:\

After the desired options have been specified, the OK button is clicked or the Enter key is pressed. The program then prompts the user for any manual actions required, including the insertion of additional diskettes during the backup procedure. Approximately 3000 results can be saved on a single high-density 3.5" diskette.

Restore Data from Floppy Disk

Saved data can be restored to the Central Data Station by using this facility. Select the drive where the backup data will be supplied and click "OK". The program will prompt when manual actions are required, and when the data restoration process has been completed.

PRINTER INSTALLATION

The Central Data Station is configured for a Canon bubble jet printer, but can be used with most printers when reconfigured properly using the Windows software. The procedure for configuring the Central Data Station for use with a printer other than the Canon bubble jet is as follows:

1. Exit the Central Data Station application by clicking on the "Exit" button. If the Program Manager is not open, double click on the Program Manager icon. If the Main group is not open, double click on the icon labeled "Main".
2. Double click on the icon labeled "Control Panel" in the Main group, and then double click on the icon labeled "Printers".
3. Double click on the name of the printer desired from the list of "Installed Printers". The name of the printer selected should then appear under "Default Printer". Click on the "Close" button, then close the Control Panel window, and double click on the i-STAT icon to restart the Central Data Station application.

   If the printer is not shown in the "list of Printers", click on the "ADD" button and scroll down the list of printers. Click on the printer desired and then click on the "Install" button. A prompt will appear requiring the insertion of a Windows disk (supplied with the Central Data Station) or a Windows driver disk supplied with the printer. Insert the disk into the A: drive and click on the "OK" button. The printer will now be listed under "Installed Printers". Click on it's name, then click on the "Set As Default Printer" button. The name of the printer should appear under "Default Printer". Click on the "Close" button, then close the Control Panel window, and double click on the i-STAT icon to restart the Central Data Station application.

i-STAT Exhibit A License Agreement—applies to all i-STAT Central Data Station Systems

"The software in this computer is licensed to the authorized user of this computer under a sub-license from i-STAT to the user. i-STAT has used the software in the computer under licenses from other original portions of software provider. By accepting and using this computer, the user/licensee agrees to the following: The user/licensee will not make copies of the software programs or any of the program software files generated by the programs, the manual or other documentation, except for archive copies made as part of user/licensee's regular back-up procedures. The user/licensee will protect the programs from unauthorized use, illegal reproduction (including reproducing any of the software files generated by the programs) or illicit distribution. The user/licensee will not change or reverse engineer the programs or any of their software files by debugging, decompiling, disassembling, reprogramming, rewriting the programs' macros, revising the programs' forms or any other means. If the user/licensee makes any use, transfer or disclosure of the programs in violation of any of the foregoing, the sub-license will, at the option of i-STAT, immediately terminate without demand or notice and the user/licensee will immediately give to i-STAT the programs, the manual and all copies thereof in the user/licensee's possession."

i-STAT warrants the licensed software and accompanying physical documentation to be free of defects for a period of thirty days from the date of installation. If notified of defects within the warranty period i-STAT will replace the defective software or documentation as soon as practicable for the nature of the defect. The remedy for breach of this warranty is limited to replacement and shall not encompass any other damages including but not limited to loss of profit, and special, incidental, consequential or other similar claims i-STAT specifically disclaims all other warranties, expressed or implied, including but not limited to implied warranties of merchantability and fitness for a particular purpose, with respect to the software, accompanying documentation and the license granted herein.

CENTRAL DATA STATION, VERSION 5

i-STAT LICENSE AGREEMENT AND WARRANTY FOR CENTRAL DATA STATION PROGRAM

License

The i-STAT Central Data Station software is licensed to the authorized user by i-STAT Corporation. Portions of the software are licensed to you by i-STAT Corporation under sublicense from other original software providers. By accepting and using this software, the user/licensee agrees to the following:

- The user/licensee will not make copies of the software programs or any of the program software files generated by the programs, the manual or other documentation except for archive copies made as part of user/licensee's regular back-up procedures.
- The user/licensee will protect the programs from unauthorized use, illegal reproduction (including reproducing any of the software files generated by the programs) or illicit distribution.
- The user/licensee will not change or reverse engineer the programs or any of their software files by debugging, decompiling, disassembling, reprogramming, rewriting the programs' macros, revising the programs' forms or any other means.

If the user/licensee makes any use, transfer or disclosure of the programs in violation of any of the foregoing, the sub-license will, at the option of i-STAT, immediately terminate without demand or notice and the user/licensee will immediately give to i-STAT the programs, the manuals and all copies thereof in the user/licensee's possession.

Warranty

i-STAT warrants the licensed software and accompanying physical documentation to be free of defects for a period of thirty days from the date of installation. If notified of defects within the warranty period, i-STAT will replace the defective software or documentation as soon as practical for the nature of the defect. The remedy for breach of this warranty is limited to replacement and shall not encompass any other damages including but not limited to loss of profit, and special, incidental, consequential or other similar claims. i-STAT specifically disclaims all other warranties, expressed or implied, including but not limited to implied warranties of merchantability and fitness for a particular purpose, with respect to the software, accompanying documentation and the license granted herein.

Software

Due to hardware requirements for proper functioning of the software, it is recommended that a PC provided by Abbott with the Central Data Station (CDS) software already installed be used. In many countries the CDS software is only available on PCs provided by Abbott. Support of CDS software on other PCs may be limited.

Caution: The use of the other software that was not provided as part of the system on the same PC with the Central Data Station software may compromise the system, including permanent loss of patient records.

Hardware

The PC on which the CDS software resides should be installed following the PC manufacturer's directions.

Connectivity

Information needed to connect the Downloaders, the portable printer and the MediSense Precision PCx Docking Station to the Point-of-Care Central Workstation are in the Download Wiring and Programming section of this manual.

Information needed to program and to connect IR Links to the Point-of-Care Central Workstation can be obtained from an Abbott representative.

Interface

Information needed to interface the CDS to an LIS or HIS can be obtained from an Abbott representative. The CDS may have to be customized for the type of interface. This procedure is described in the Interface Program Customization section of the manual.

Site Specific Customization of the CDS

During installation, the CDS must be customized to properly communicate with i-STAT 1 Downloaders, i-STAT IR Links and Agilent Technologies Blood Analysis Modules throughout the hospital. The procedure to customize the CDS is described under the Customization section below.

Activation of the Precision PCx Glucose Test Strip Method

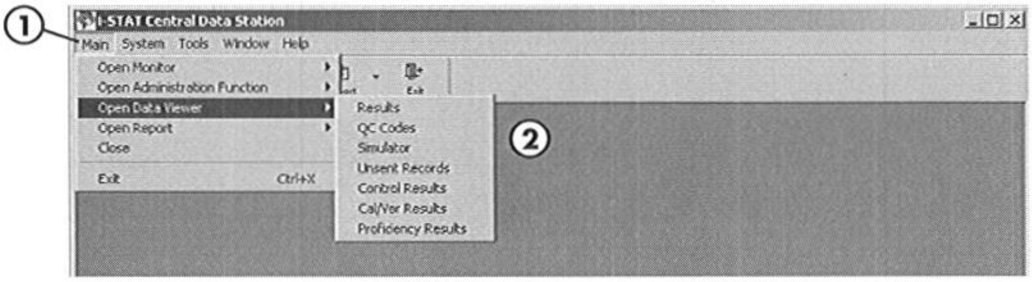
Contact your Customer Support representative to activate the MediSense Precision PCx glucose test strip method for the i-STAT 1 Analyzer on the Central Data Station.

Overview

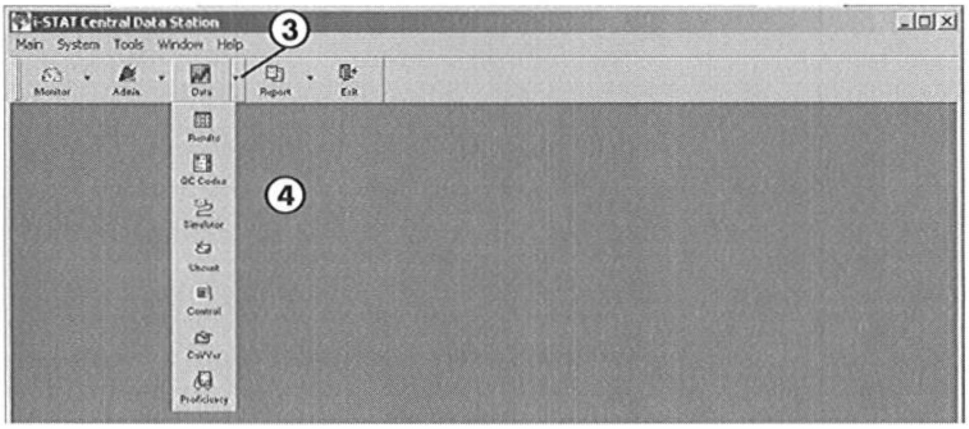
The CDS software follows typical Microsoft® Windows® conventions and procedures. The illustrations below are used to point out the use of the menu bar, toolbars, tabs and buttons.

Selecting Menu Options

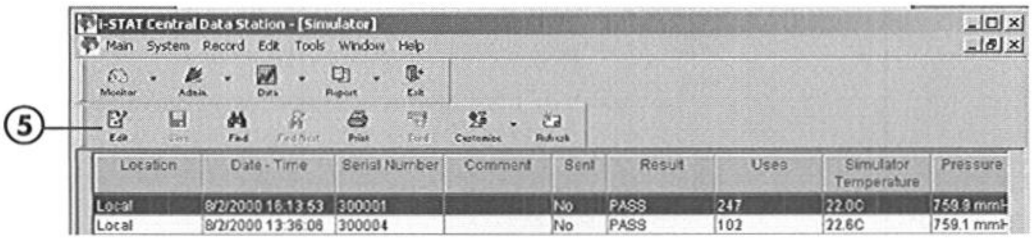
Clicking an item on the menu bar (1) will drop down the menu for that item. If any of the items in the drop down menu has a submenu, the submenu will open to the right of the ▶symbol next to the item when the item is highlighted (2).


①
i-STAT Central Data Station
Main System Tools Window Help
Open Monitor
Open Administration Function
Open Data Viewer
Open Report
Close
Exit Ctrl+X
Results
QC Codes
Simulator
Unsent Records
Control Results
Cal/Ver Results
Proficiency Results
Exit
②

Clicking the ▼ beside a toolbar button (3) will drop down a submenu toolbar (4).


i-STAT Central Data Station
③
Main System Tools Window Help
Monitor
Admin
Data
Report
Exit
Results
QC Codes
Simulator
Unsent
Control
Cal/Ver
Proficiency
④

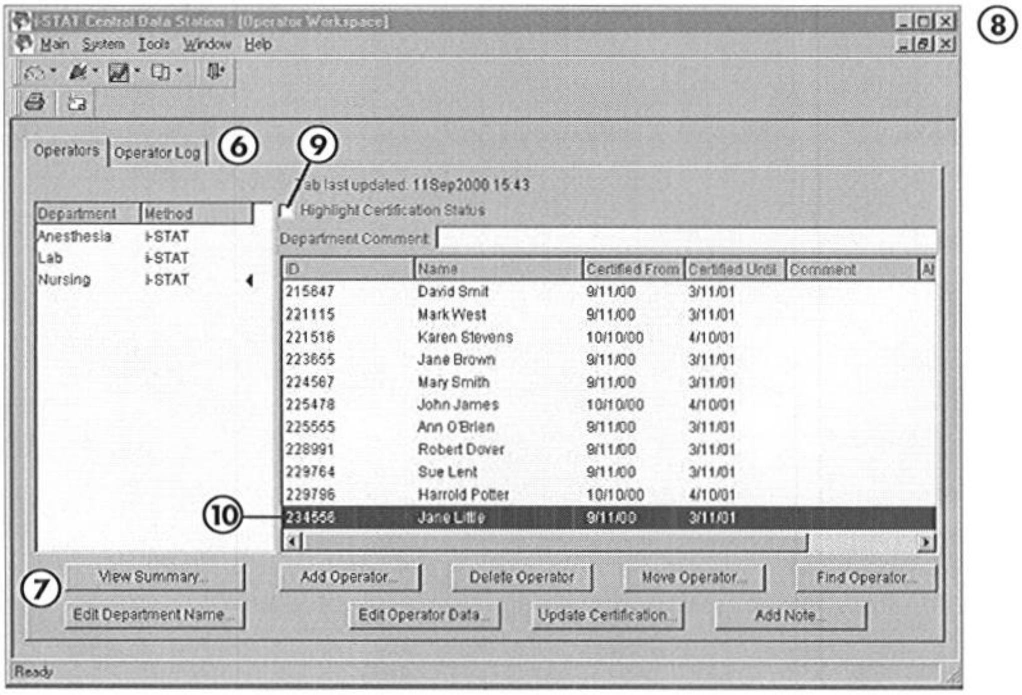
Clicking the desired menu option will open the item's window or will perform the item's function. The menu items and toolbar for the active window will be displayed (5).


i-STAT Central Data Station - [Simulator]
Main System Record Edit Tools Window Help
Monitor
Admin
Data
Report
Exit
⑤
Edit
Save
Find
Find Next
Print
Send
Customize
Refresh

Location	Date - Time	Serial Number	Comment	Sent	Result	Uses	Simulator Temperature	Pressure
Local	8/2/2000 16:13:53	300001		No	PASS	247	22.0C	759.8 mm
Local	8/2/2000 13:36:08	300004		No	PASS	102	22.6C	759.1 mm

Selecting Functions in a Window

Tabs: A window may have several functional groupings that are contained in tabs with multiple pages (6). Clicking the text on the tab will display the corresponding page.


i-STAT Central Data Station - [Operator Workspace]
Main System Tools Window Help
Operators
Operator Log
⑥
⑨
⑩
⑦
⑧
View Summary...
Edit Department Name...
Add Operator...
Delete Operator
Move Operator...
Find Operator...
Edit Operator Data...
Update Certification...
Add Note...
Ready

Tab last updated: 11Sep2000 15:43

☐ Highlight Certification Status

Department Comment:

Department	Method
Anesthesia	i-STAT
Lab	i-STAT
Nursing	i-STAT

ID	Name	Certified From	Certified Until	Comment	Al
215847	David Smit	9/11/00	3/11/01		
221115	Mark West	9/11/00	3/11/01		
221516	Karen Stevens	10/10/00	4/10/01		
223655	Jane Brown	9/11/00	3/11/01		
224567	Mary Smith	9/11/00	3/11/01		
225478	John James	10/10/00	4/10/01		
225565	Ann O'Brien	9/11/00	3/11/01		
228991	Robert Dover	9/11/00	3/11/01		
229764	Sue Lent	9/11/00	3/11/01		
229796	Harrold Potter	10/10/00	4/10/01		
234556	Jane Little	9/11/00	3/11/01		

Buttons: Use to activate a function within a window (7) or to confirm (OK) or cancel a function or to manipulate a window. All windows can have the following buttons in the upper right hand corner (8):

□	This button causes the window to be maximized.
_	This button causes the window to be minimized.
🗗	This button causes the window to be moveable and resizable.
✕	This button causes the window to close.

If a window does not have a close button, it can be closed by selecting **Main** then **Close** on the menu bar.

Check boxes: Click the box to enable or disable a single option (9).

Radio buttons: Click the circle to select from a list of mutually exclusive options.

Highlight bar: Use to select the line or lines on which to apply a function (10).

Drop down list: Click the ▼ button to drop down a list or scroll downward in a window.

Refreshing/ Updating the Data in a Window

The **Refresh** toolbar button refreshes the data content in the active window with the most recent data available. The refresh function is also available under the Window option on the menu bar. Pressing **F5** will also refresh the data.

Sorting Data in a Window

In most cases, when data is presented in a table, clicking a column header will sort the display based on the data in that column. In the Data Viewers, repeating values, such as a patient ID, will be sorted in descending Date/Time order. Clicking the header again will reverse the order of the sort. To return the data to chronological order, click the Date-Time column header.

Selecting Multiple Lines

In many functions, multiple lines can be selected for the desired action. To select consecutive multiple lines, click the first line and, while holding down the **Shift** key, click the last line. To select multiple lines that are not consecutive, click the desired lines while holding down the **Ctrl** key.

Opening Multiple Windows

Multiple windows can be open at the same time. The **Windows** item on the menu bar can be used to select the desired window from the list of open windows and bring it to the forefront. Close windows by clicking the **Close** button at the top right of the window or by selecting **Close** from the **Main** menu.

Column Ordering

Columns in the Data Viewers can be placed in any order. Use the mouse to grab a column header and drag the column to the desired position.

Column Widths

To adjust a column's width in Data Viewers, place the mouse pointer on the edge of the column header. When the mouse pointer turns into two arrows, hold the left mouse key and drag column to the desired width.

Toolbars

Select **Tools**, then **Customize Toolbars** to select options for the way toolbars appear. Selecting **Large Buttons** displays descriptive text under toolbar buttons. This may be helpful while learning the application. Selecting **Show Tooltips** displays a description of a button when the mouse pointer is placed over a toolbar button.

CUSTOMIZATION OF THE CENTRAL DATA STATION

Overview

The Customization options are:

Site Information	Institution name and technical support phone number
Serial Ports	Enables/Disables serial communications and allows individual ports to be selected and configured
Network	Enables/Disables network communications and allows specification of TCP port numbers
Interface	Enables/Disables external interfacing and allows protocol to be selected
Options	Allows various general system behaviors to be specified

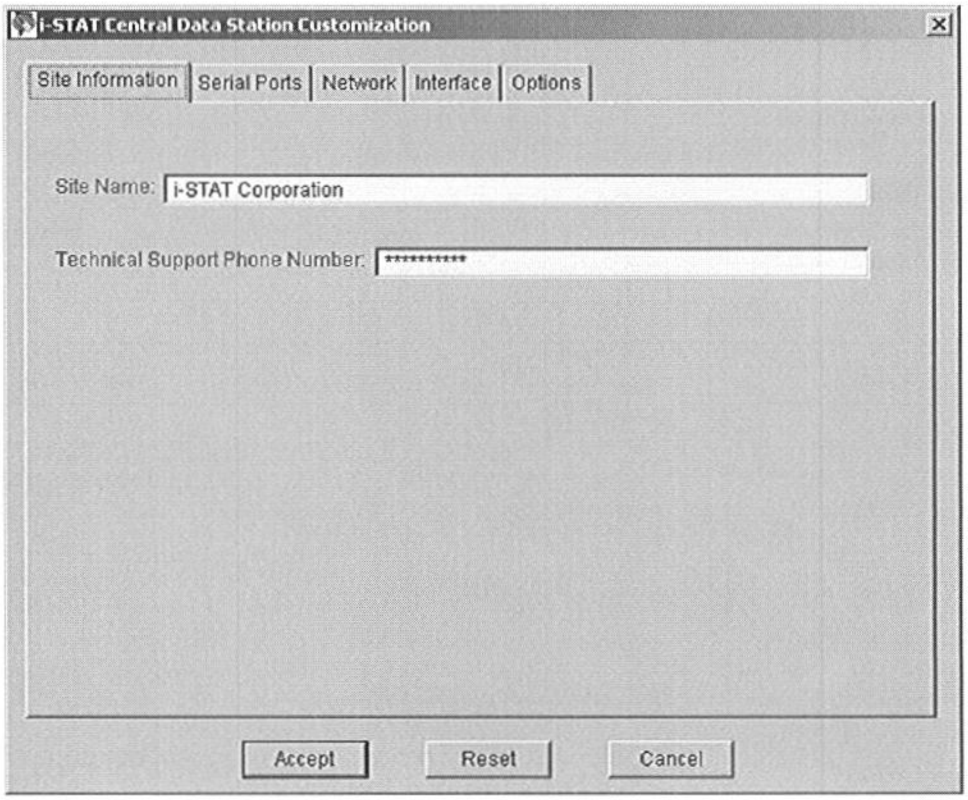
To access the Customization screen, close the CDS application, access the Run dialog box by clicking **Start**, then **Run**. Type **wcds32 config** at the **Open:** prompt, then click **OK**.

When the Customization screen appears, click a tab to display the desired tab page. The information in each field can be specified. When all tabs are customized as desired, click the **Accept** button to save the information. Click the **Reset** button to disregard changes and restore the previous information. Click the **Cancel** button to ignore any changes and retain the current settings. When customization is complete, the CDS application will open automatically.

Site Information

A site name and address of up to 60 characters can be entered into this field.

The appropriate Technical Support Phone Number for the country will be listed or can be entered.


i-STAT Central Data Station Customization
Site Information
Serial Ports
Network
Interface
Options
Accept
Reset
Cancel

Site Name: i-STAT Corporation

Technical Support Phone Number: ***********

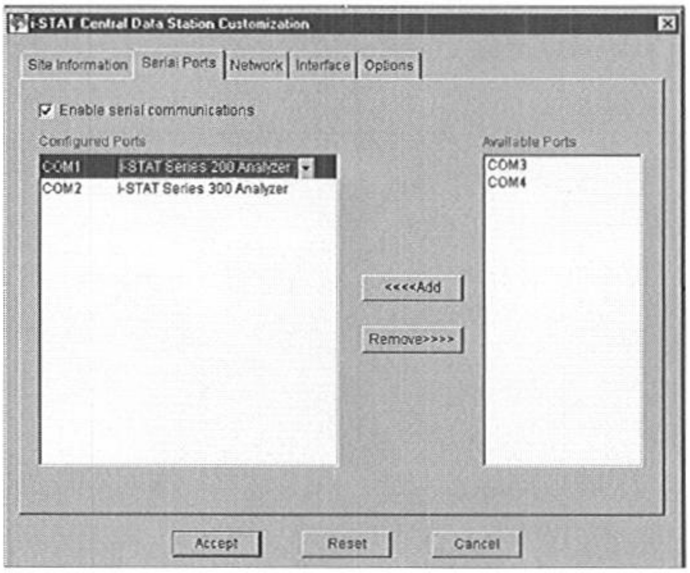
Serial Ports

The Central Data Station program resides on a PC with multiple serial ports (DB9). Available ports will automatically be listed under **Available Ports** on the Serial Ports tab page. The following components can be connected to the Central Data Station via serial ports:

- ☐ **i-STAT Series 200 Analyzer:** IR Link transmits data to and from the i-STAT Portable Clinical Analyzer. A serial connection to the CDS is needed for software updates when JAMS software is included in the update.
- ☐ **i-STAT Series 300 Analyzer:** Downloader transmits data to and from the i-STAT 1 Analyzer. A serial connection to the CDS is needed for software updates when JAMS software is included in the update.
- ☐ **HP Module:** a local connection to the CDS is needed to transmit software updates and customization profiles to the Agilent Technologies Blood Analysis Module.
- ☐ **HP PDS:** The Agilent Technologies Patient Data Server transmits patient data from the Blood Analysis Module to the CDS.

Click the **Enable serial communications** box to check it and enable serial communications.

Click the desired port(s) under **Available Ports** and click the **<<<<Add** button. The port(s) will now be listed under **Configured Ports.**



i-STAT Central Data Station Customization

☑ Enable serial communications

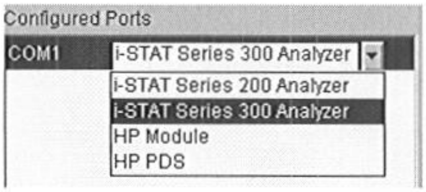
Configured Ports

COM1 i-STAT Series 200 Analyzer
COM2 i-STAT Series 300 Analyzer

Available Ports

COM3
COM4

Click the port and select an instrument for that port.



Configured Ports

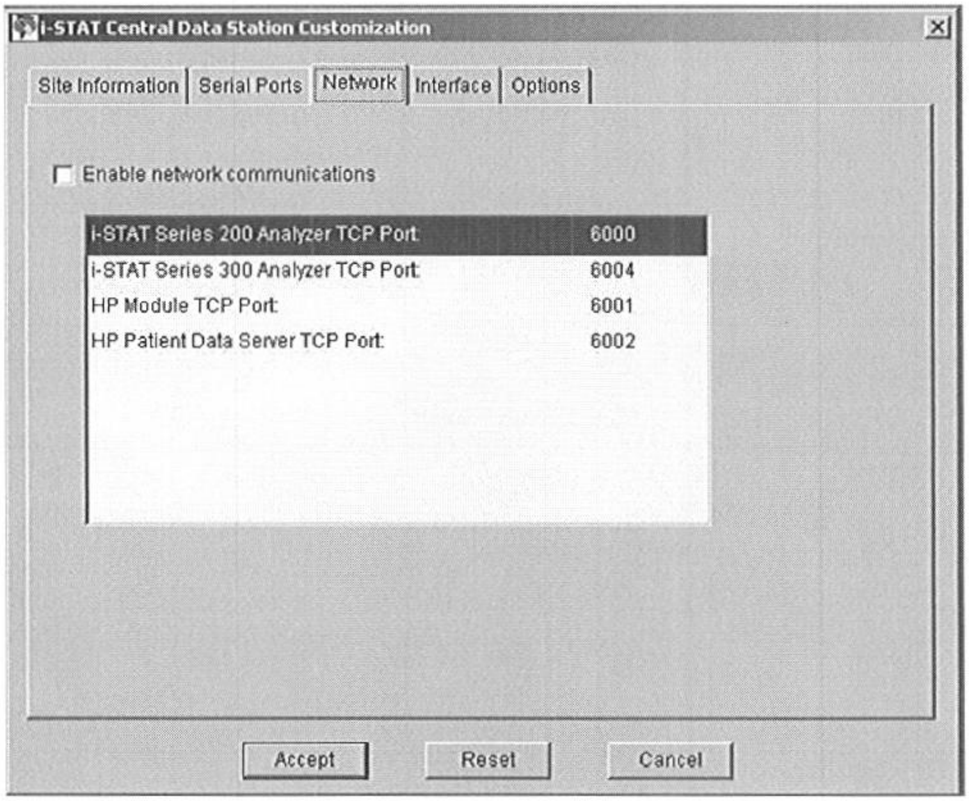
COM1 i-STAT Series 300 Analyzer

Serial ports on the PC might also be needed for a local PCx Docking Station and connection to an interface.

Network

Click the **Enable network communications** box to check it and enable network communications.

The default TCP service port assignments are listed in the Network tab page. If not using the default ports, click the port and type in the new assignment. Port numbers need to be in the range of 1024 to 65535.



i-STAT Central Data Station Customization
Site Information
Serial Ports
Network
Interface
Options
Accept
Reset
Cancel

☐ Enable network communications

i-STAT Series 200 Analyzer TCP Port:	6000
i-STAT Series 300 Analyzer TCP Port:	6004
HP Module TCP Port:	6001
HP Patient Data Server TCP Port:	6002

Note: If a PCx Docking Station is sharing the ethernet port with an i-STAT Downloader, the PCx port assignment is made in QC Manager.

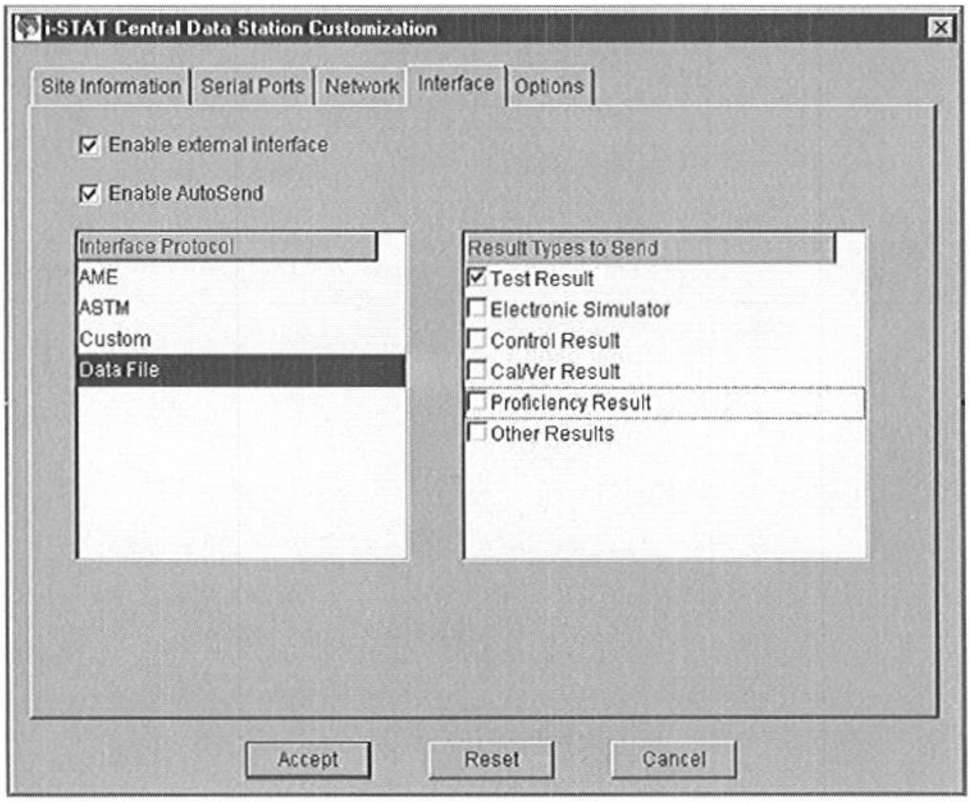
Interface

The appropriate interface protocol and the types of records to be sent to another data management system are selected in the Interface page. At this time, the AME and Data File options are active. This configuration will typically be done by the interface provider.

- ☐ **AME:** Automatic Manual Entry – installed by i-STAT Corporation.
- ☐ **ASTM:** Data transmission conforms to ASTM E1381-95 and ASTM E1394-97 standards.
- ☐ **Custom:** Not supported at this time.
- ☐ **Data File:** Formats the CDS data for third party use.

Click **Enable external interface** box to check it and enable this function.

Click **Enable AutoSend** box to check it and enable this function. When AutoSend is enabled, records will be automatically sent from the Central Data Station to another data management system whenever they are received by the Central Data Station. Checking this box will cause the CDS program to start up with AutoSend enabled on start-up. AutoSend can be temporarily enabled/disabled from the CDS program as well. Records can also be sent manually from the Data Viewers.



☑ Enable external interface

☑ Enable AutoSend

Interface Protocol
- AME
- ASTM
- Custom
- Data File

Result Types to Send
- ☑ Test Result
- ☐ Electronic Simulator
- ☐ Control Result
- ☐ Cal/Ver Result
- ☐ Proficiency Result
- ☐ Other Results

Options

Confirmation message on exit: When this option is enabled, a confirmation message is displayed prior to exiting the CDS program.

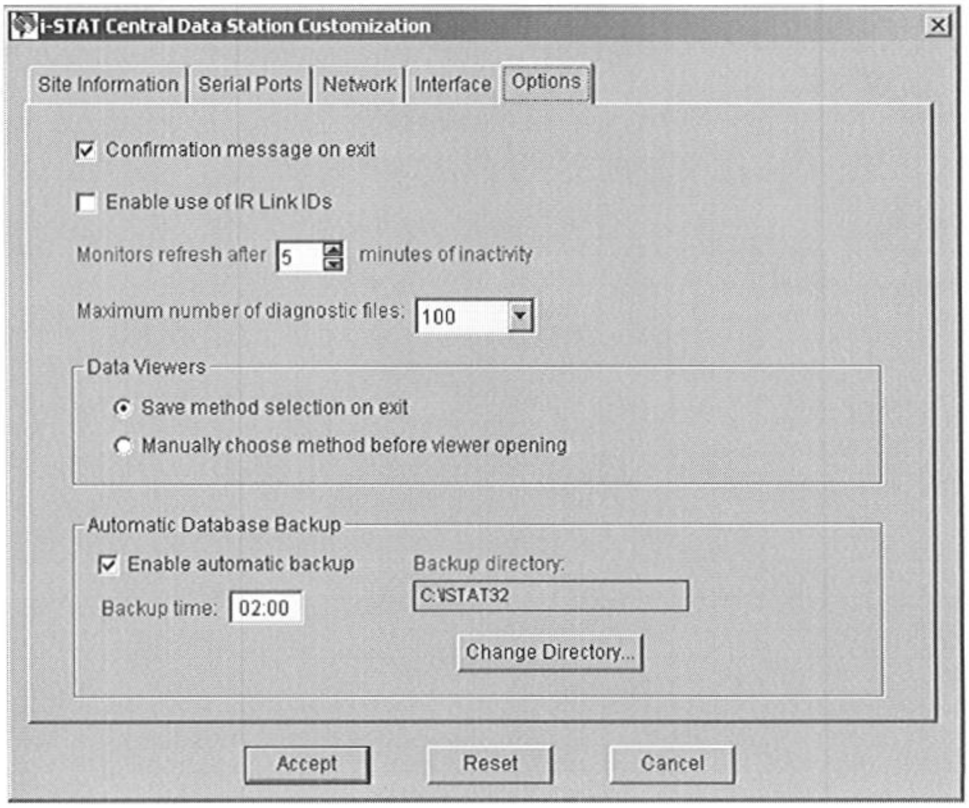
Enable use of IR Link IDs: When enabled, the IDs programmed into the IR Links are used in determining the download location of the results instead of the actual serial port or IP address. To use this function, all IR Links must be of the self-identifying type. This option is not typically used but is available in case the functionality is needed.

Monitor refresh: The status reports in the Download and Interface Monitors will be updated after the period of inactivity specified.

Maximum diagnostic files: Diagnostic files contain information that can be useful in troubleshooting cartridge problems. The default number is 100 and is changed at the request of a Customer Support representative.

Data Viewers: Selecting **Save method selection on exit** will cause each Data Viewer to save whichever method was selected when the viewer is closed or the **Exit** button clicked. The next time the viewer or CDS software is opened, the saved method will be displayed. When **Manually choose method before viewer opening** is selected, the user will be prompted to choose a method before a data viewer is opened.

Automatic Database Backup: When enabled, the CDS database files will be backed up to the selected directory at the time of day entered. Should there be a malfunction resulting in the corruption of the database, a Customer Support representative may be able to retrieve the lost data from the backup copy. Each backup replaces the previous one. Backup time depends on the size of the database but usually does not take longer than 15 minutes.



☑ Confirmation message on exit

☐ Enable use of IR Link IDs

Monitors refresh after 5 minutes of inactivity

Maximum number of diagnostic files: 100

Data Viewers

● Save method selection on exit

○ Manually choose method before viewer opening

Automatic Database Backup

☑ Enable automatic backup

Backup time: 02:00

Backup directory: C:\ISTAT32

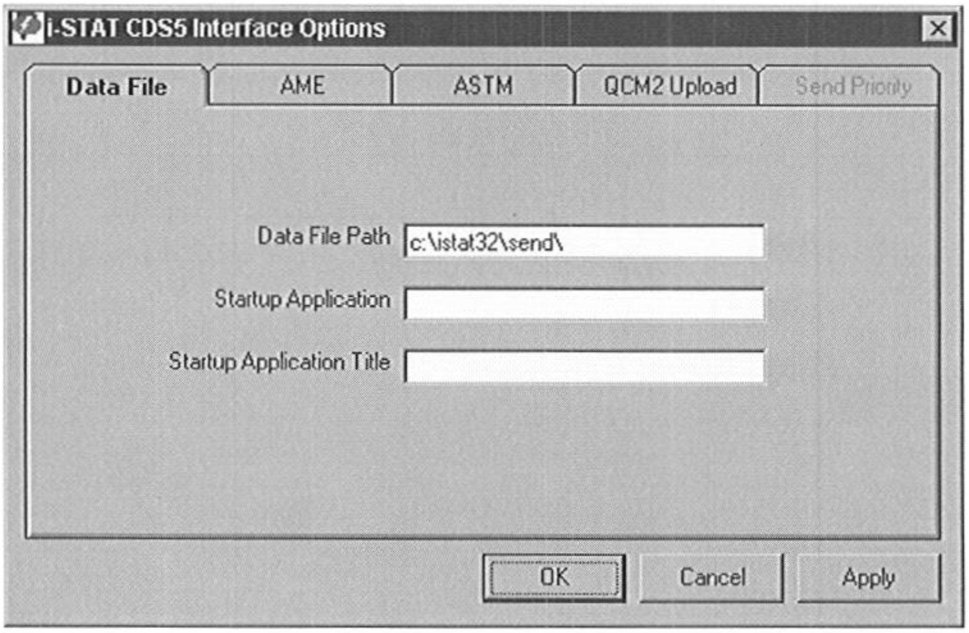
Overview

The Central Data Station can output results to an external computer system such as an LIS or HIS. The Central Data Station also provides a function that, when enabled, will also transmit all of the Precision PCx results generated on the i-STAT 1 Analyzer to QC Manager so they can be managed as part of the overall Blood Glucose Testing program.

The Central Data Station needs to be customized for the interface type using the procedures below. Tabs are presented for the options available. Each tab represents a protocol that the Interface Component of the CDS supports. Depending on the particular installation, one or more of these will be used.

Procedure

1. Exit the CDS program.
2. Click **Start** then **Run.**
3. Type **C:\istat32\bin\interface32.exe.**
4. Click **OK.**
5. Click **File**, then **Options**. The following screen will be displayed.



Data File Path: c:\istat32\send\

Startup Application:

Startup Application Title:

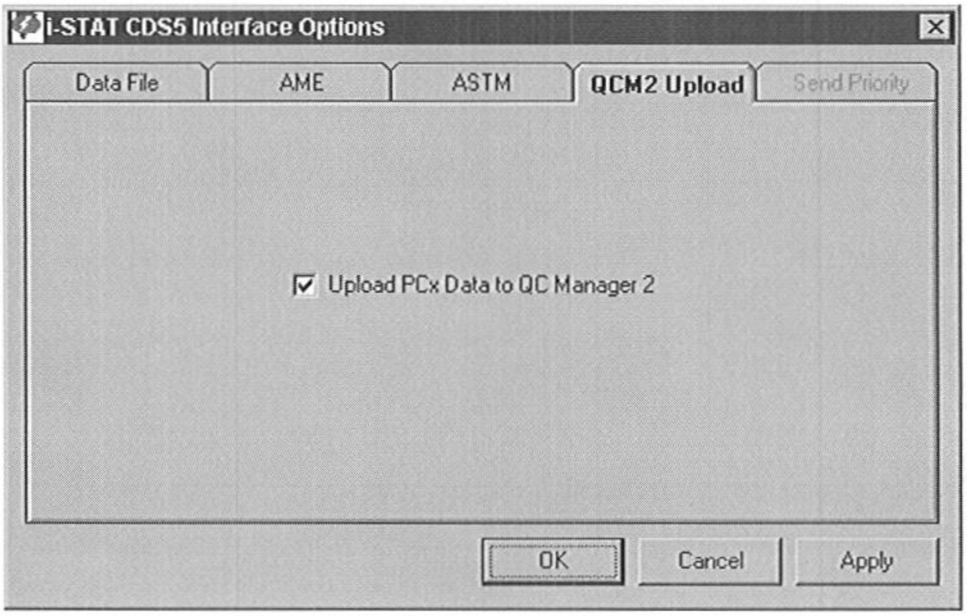
These tabs are used by the interface provider to configure the Interface Component of the CDS for the protocol that will be used.

QCM2 Upload Tab

When MediSense Precision PCx glucose test strips are being run on the i-STAT 1 Analyzer, the glucose test strip data can be made available to QC Manager data management program.

When enabling this option in the Interface Program Customization, an Interface Protocol must be selected on the Interface Tab in the Central Data Station Customization and the following must be checked under Result Types to Send: Test Result, Control Result, Cal/Ver Result and Proficiency Result.

Click the **QCM2 Upload** tab and click to enter a checkmark in the box for **Upload PCx Data to QC Manager 2** to enable this function.


i-STAT CDS5 Interface Options
Data File
AME
ASTM
QCM2 Upload
Send Priority
OK
Cancel
Apply

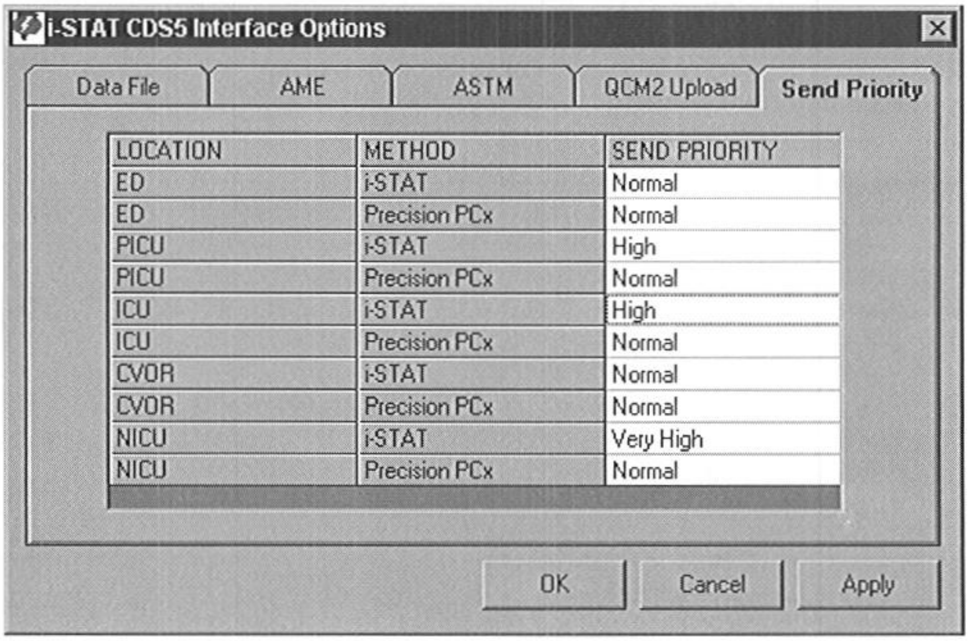
☑ Upload PCx Data to QC Manager 2

Send Priority

This function will prioritize the queue of results in the CDS database being processed by the Interface Component of the CDS program. This capability can be used by the interface provider to prioritize handling of results from one location over another.

Procedure

1. The CDS program must be running and the external interface must be enabled.
2. Click the i-STAT CDS Interface button on the taskbar at the bottom of the display to open the interface program's main window.
3. Click **File**, then **Options**.
4. Click the **Send Priority** tab. (The other tabs will be available for viewing only.)
5. Click the Location/Method line to prioritize.
6. Right click under the **Send Priority** column and select the priority: Normal, High, Very High, from the drop down list.
7. Click **OK** to finish.



LOCATION	METHOD	SEND PRIORITY
ED	i-STAT	Normal
ED	Precision PCx	Normal
PICU	i-STAT	High
PICU	Precision PCx	Normal
ICU	i-STAT	High
ICU	Precision PCx	Normal
CVOR	i-STAT	Normal
CVOR	Precision PCx	Normal
NICU	i-STAT	Very High
NICU	Precision PCx	Normal

Overview of the Central Data Station Program

The Central Data Station (CDS) software includes the following point-of-care testing process management functions:

- Managing instruments
- Managing operators
- Managing policy compliance
- Monitoring operator competence
- Managing LIS entry exceptions
- Reviewing patient and quality results

These functions are listed under the main menu option in four main groupings: monitors, viewers, workspaces and reports.

Central Data Station Software Function Overview and Toolbar Buttons

- Monitor
    - Download
    - Interface
- Administration Tools (Workspaces)
    - Instrument/Location
    - Operator
    - Database Maintenance
    - Customization
- Data Viewer
    - Results (patient)
    - QC Codes
    - Simulator
    - Unsent Records
    - Control Results
    - Calibration Verification
    - Proficiency Tests
- Report
    - Reagent Management
    - Method Competence
    - Method Compliance

INSTRUMENT AND LOCATION WORKSPACE

Overview

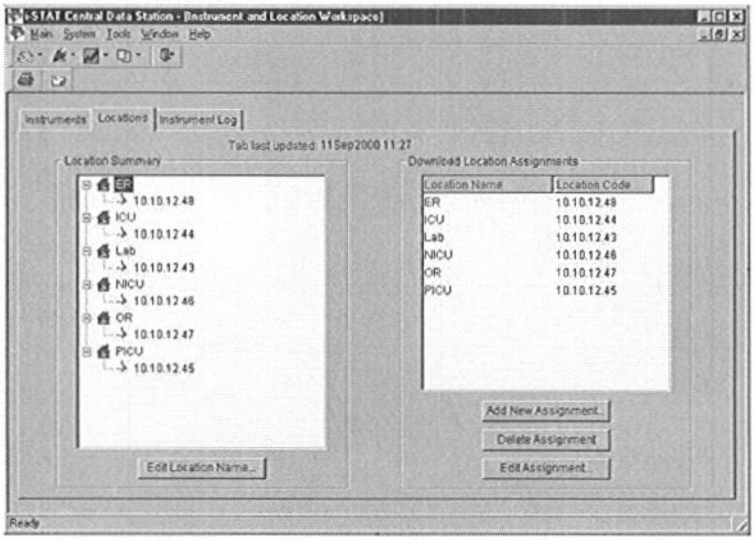
This workspace is used to:

- assign names to download locations,
- assign instruments to locations, and
- set required download intervals for each location.

The following sequence of tasks is used to set up the Central Data Station's management function for instruments:

1. Assign Location Names to Location Codes. Location Codes are the physical port addresses for the download devices.
2. Assign Instruments to Download Locations.

Locations


i-STAT Central Data Station - [Instrument and Location Workspace]
Main System Tools Window Help
Instruments
Locations
Instrument Log
Location Summary
ER
10.10.12.48
ICU
10.10.12.44
Lab
10.10.12.43
NICU
10.10.12.46
OR
10.10.12.47
PICU
10.10.12.45
Edit Location Name...
Download Location Assignments
Add New Assignment...
Delete Assignment
Edit Assignment...
Ready

Tab last updated: 11Sep2000 11:27

Location Name	Location Code
ER	10.10.12.48
ICU	10.10.12.44
Lab	10.10.12.43
NICU	10.10.12.46
OR	10.10.12.47
PICU	10.10.12.45

☐ Edit Location Name...

The location name can be changed from a letter/number code to the name of a nursing unit, department, site, etc.. Up to 17 characters can be used to identify a location.

Note: Interface logic should be considered before editing.

☐ Add New Assignment...

Download locations can be added manually using the **Add New Assignment...** button. Download locations will also be added automatically when a transmission is received from a download device with a location that is not already on the list. The name assigned is A_xx, where xx is the download device's IP address or serial port. This name can be changed by selecting Edit Assignment.

To assign instruments to a location without a download device, enter a Location Name or another descriptive word as the Location Code.

- ☐ Delete Assignment

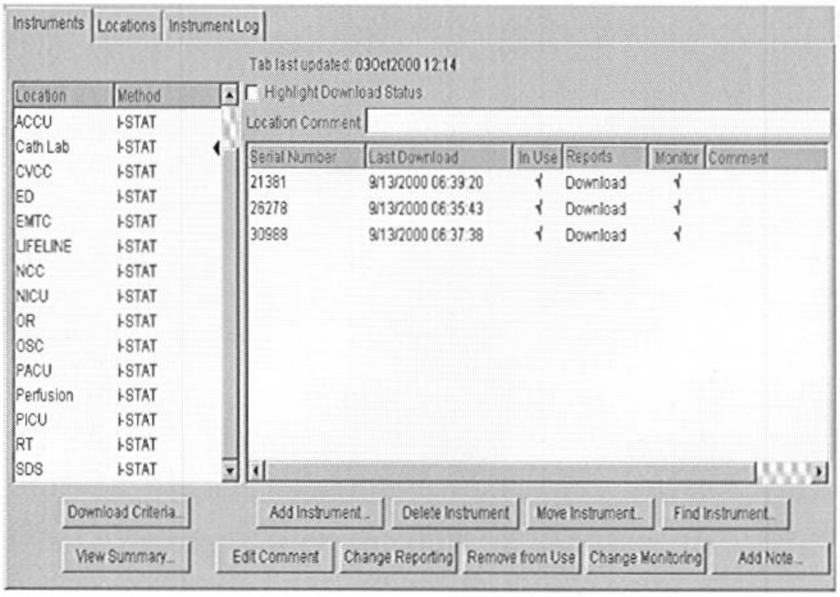
Click the location name and code and then click the **Delete Assignment** button.

- ☐ Edit Assignment...

Click the location name to be changed, click the **Edit Assignment...** button and enter a new location name of up to 17 characters or chose from the drop down list.

Instruments

Once download locations are assigned to locations, the Instruments tab page will be the focus of management activities.


Instruments
Locations
Instrument Log
☐ Highlight Download Status
Location Comment
Download Criteria...
View Summary...
Add Instrument...
Delete Instrument
Move Instrument...
Find Instrument...
Edit Comment
Change Reporting
Remove from Use
Change Monitoring
Add Note...

Tab last updated: 03Oct2000 12:14

Location	Method	
ACCU	I-STAT	
Cath Lab	I-STAT	◄
CVCC	I-STAT	
ED	I-STAT	
EMTC	I-STAT	
LIFELINE	I-STAT	
NCC	I-STAT	
NICU	I-STAT	
OR	I-STAT	
OSC	I-STAT	
PACU	I-STAT	
Perfusion	I-STAT	
PICU	I-STAT	
RT	I-STAT	
SDS	I-STAT	

Serial Number	Last Download	In Use	Reports	Monitor	Comment
21381	9/13/2000 06:39:20	✓	Download	✓	
26278	9/13/2000 06:35:43	✓	Download	✓	
30988	9/13/2000 06:37:38	✓	Download	✓	

- ☐ Location

Instruments are assigned to locations. This assignment can be made when an instrument is manually added in the Instruments page or when an instrument downloads to the Central Data Station for the first time.

- ☐ Method

The CDS is designed to accept results from any instrument that can be downloaded to the CDS program. The i-STAT method in the Instrument window refers to the i-STAT Portable Clinical Analyzer, the i-STAT 1 Analyzer (both i-STAT cartridge and MediSense Precision PCx Glucose Test Strip) and the Agilent Technologies Blood Analysis Module.

Clicking a Location/Method on the left side of the window will list the status of all instruments for that location and method in the right side of the window. A ◄ symbol indicates which location and method has been selected.

☐ Highlight Download Status

Checking this box will highlight locations with instruments that have exceeded the required interval for downloading as well as noncompliant instruments within the location selected.

☐ Download Criteria...

Compliance to download policy can be monitored by the CDS program. Criteria for download compliance is set using the **Download Criteria...** button. Compliance with the criteria can be observed by checking the Highlight Download Status check box or by going to the Download Monitor. Individual Download criteria can be set for each location and method pair.

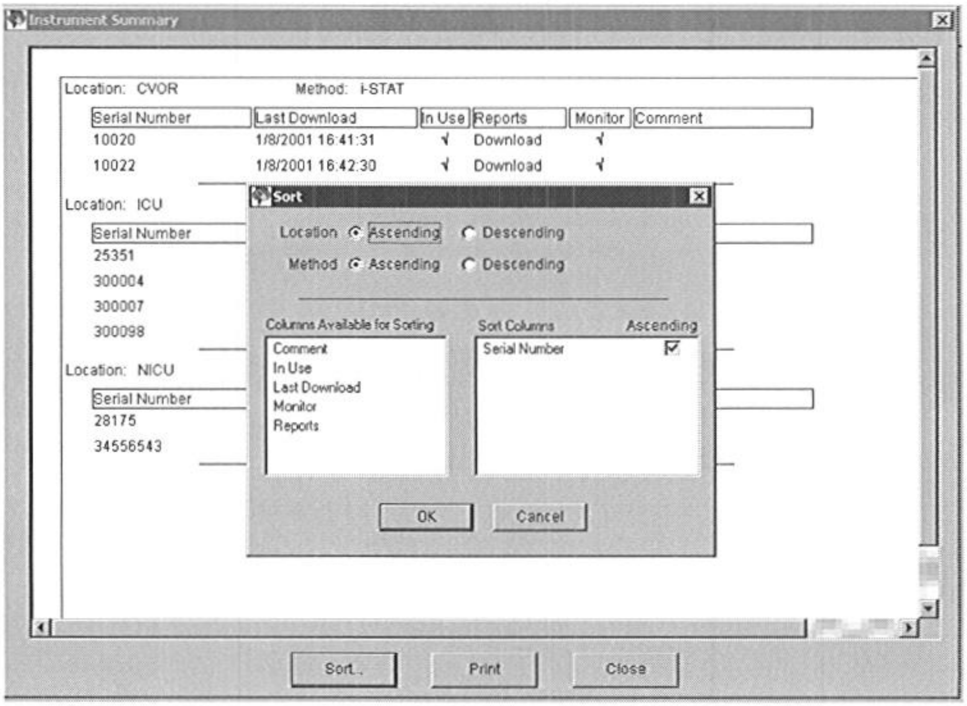
Click the desired Location/Method and then click the **Download Criteria...** button. Use the up and down arrow buttons to select the criteria in hours or manually enter the hours. An interval of up to 1000 hours is allowed.

Note: The i-STAT 1 Analyzer can also be customized either to warn the end users that a download is required or to lockout end users if the time for a download has been reached or exceeded. The download criteria for analyzers and for the CDS monitor should be selected to make sense.

☐ View Summary...

The View Summary provides a report of the current instrument assignments and the last download for each instrument. Summaries can be viewed and printed by:

- This method and location only (location and method selected with ◄ symbol)
- This method, all locations (method selected with ◄ symbol)
- All methods, all locations



Location: CVOR Method: i-STAT

Serial Number	Last Download	In Use	Reports	Monitor	Comment
10020	1/8/2001 16:41:31	✓	Download	✓	
10022	1/8/2001 16:42:30	✓	Download	✓	

Location: ICU

Serial Number
25351
300004
300007
300098

Location: NICU

Serial Number
28175
34556543

Location ● Ascending ○ Descending

Method ● Ascending ○ Descending

Columns Available for Sorting: Comment, In Use, Last Download, Monitor, Reports

Sort Columns	Ascending
Serial Number	☑

☐ Add Instrument...

The Add Instrument window is used to add an instrument to the system. Enter the Serial Number of the instrument and select the Method. **Select the i-STAT method for the i-STAT 1 Analyzer both cartridge and test strip.** Then select a location from the dropdown list.

If the location is not listed, add the location using the **Add New Assignment...** button in the Locations tab page. If the location does not have a download device associated with it, such as an instrument used for transporting patients, a location name can be typed in. (In this case the Location Code on the Locations tab page will be SYSCODExxxxxx.) Up to 17 characters can be used.

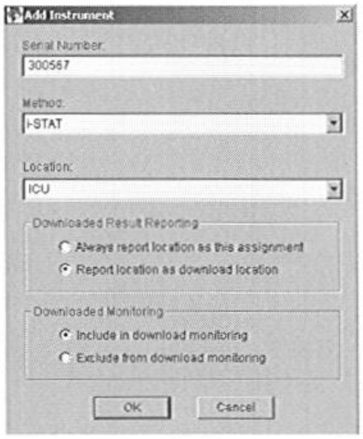
There are two options for Download Result Reporting:

1. **Always report location as this assignment:** The results from this instrument will appear with the location of the instrument's assignment regardless of the download device used to transmit the results. This option is useful when an instrument is assigned to a functional group that may download from various areas in the institution. The instrument will be designated "Assignment" under the Reports column in the Instruments tab page.

2. **Report location as download location:** The results from this instrument will appear with the location for the download device that was used to transmit results to the Central Data Station. The instrument will be designated "Download" under the Reports column on the Instruments tab page.

   If the instrument is not manually added to the list and it transmits to the CDS, it is automatically assigned to the location of the download device and is set to report "Download." If the download device location has not been manually added, a default location A_xx (B_xx, C_xx, etc.), where xx is the IP address or serial port of the download device, will be used.

There are two options for Download monitoring:



Serial Number: 300567

Method: i-STAT

Location: ICU

Downloaded Result Reporting
○ Always report location as this assignment
● Report location as download location

Downloaded Monitoring
● Include in download monitoring
○ Exclude from download monitoring

1. **Include in download monitoring:** Includes this Serial Number in download monitoring.

2. **Exclude download monitoring:** The download status of the instrument will not be reported by the Download Monitor. (Blood Analysis Modules and infrequently used analyzers might be exempted from the Download Monitor report).

☐ Delete Instrument

Click the Location/Method for the instrument to be deleted and then on the serial number of the instrument to be deleted. Click the **Delete Instrument** button.

☐ Move Instrument...

Click the Location/Method for the instrument to be moved and then on the serial number of the instrument to be moved. Click the **Move Instrument...** button and select the new location from the drop down list or type in a new location.

☐ Find Instrument...

Click the **Find Instrument...** button, enter the serial number of the instrument and select the Method from the drop down list.

☐ Edit Comment

Click the instrument serial number, Click the **Edit Comment** button and enter a comment of up to 16 characters.

☐ Change Reporting

Click the instrument serial number. Click the **Change Reporting** button to toggle the between Download and Assignment.

☐ Remove from Use

Click the instrument serial number. If there is a checkmark in the In Use column, clicking the **Remove from Use** button will remove the checkmark. If there is no checkmark in the In Use Column, the button will be labeled **Put in Use.**

Instruments that are not checked "In Use" do not have a download criteria applied to them. You would use this for instruments you do not expect to be downloaded. When an analyzer that is not marked "in use" downloads, it is set back in use and the download criteria is applied.

☐ Change Monitoring

Click the instrument serial number and click the **Change Monitoring** button to add or remove the check mark from the Monitor column.

☐ Add Note

A note of up to 50 characters can be entered. The note will appear as a Log Entry in the Instrument Log tab page.

Instrument Log

The Instrument Log tracks all changes made in the Instruments tab page. Additional comments can be added to the log by clicking the **Add Note** button in the Instruments tab page.

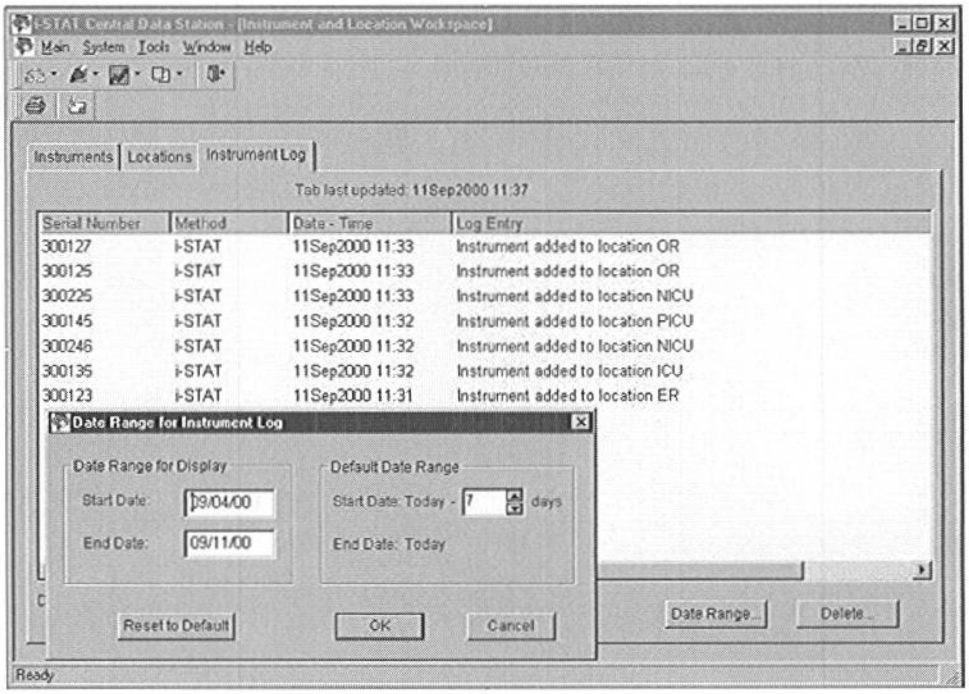
☐ Date Range...

Data can be viewed within a user defined default range or by a manually entered range.

☐ Delete...

The **Delete** button allows selected or all entries within the date range selected to be deleted.

To print the log press the **F2** key or select **Print** from the Main menu or toolbar.


i-STAT Central Data Station - [Instrument and Location Workspace]
Main System Tools Window Help
Instruments
Locations
Instrument Log
Date Range for Instrument Log
Reset to Default
OK
Cancel
Date Range...
Delete...
Ready

Tab last updated: 11Sep2000 11:37

Serial Number	Method	Date - Time	Log Entry
300127	i-STAT	11Sep2000 11:33	Instrument added to location OR
300125	i-STAT	11Sep2000 11:33	Instrument added to location OR
300225	i-STAT	11Sep2000 11:33	Instrument added to location NICU
300145	i-STAT	11Sep2000 11:32	Instrument added to location PICU
300246	i-STAT	11Sep2000 11:32	Instrument added to location NICU
300135	i-STAT	11Sep2000 11:32	Instrument added to location ICU
300123	i-STAT	11Sep2000 11:31	Instrument added to location ER

Date Range for Display
Start Date: 09/04/00
End Date: 09/11/00

Default Date Range
Start Date: Today - 7 days
End Date: Today

OPERATOR WORKSPACE

Overview

This workspace is used to:

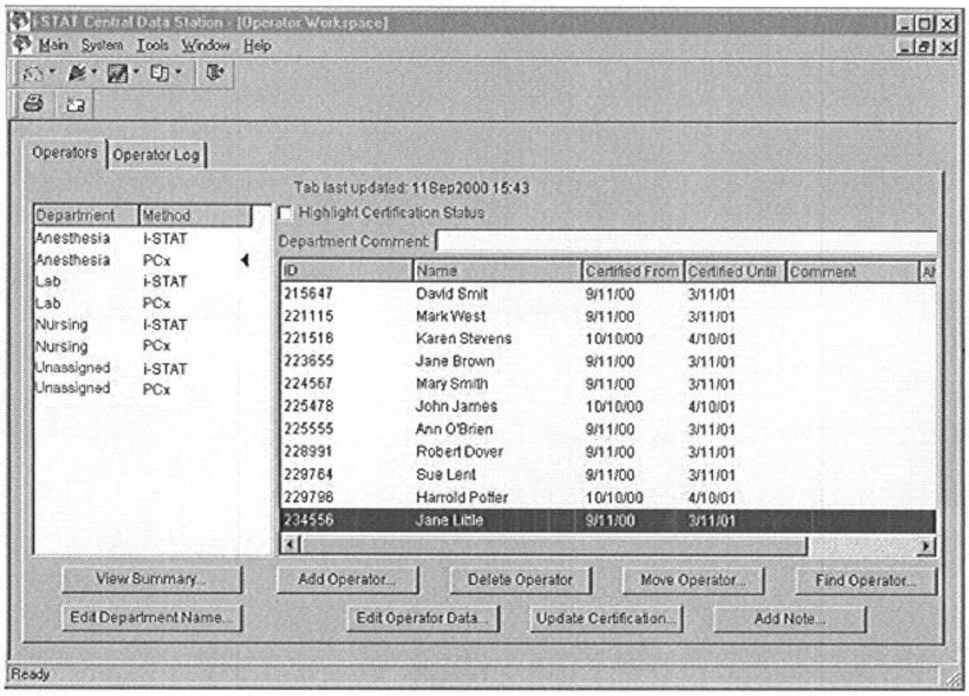
- Record operator names and identification numbers
- Record certification dates and certification expiration dates
- Assign operators to departments
- Add comments

When the i-STAT 1 Analyzer is customized to use the operator list created here, the analyzer can be customized to warn or lockout operators if they are not on the list or their certification has expired.

Operators

Operators are listed by Department and Method as indicated by the *f* symbol. Operators are added to the operator list by department and by method.

When a record is received with an Operator ID that is not listed in any Department, the operator is placed in the "Unassigned" department.


i-STAT Central Data Station - [Operator Workspace]
Main
System
Tools
Window
Help
Operators
Operator Log
View Summary...
Edit Department Name...
Add Operator...
Delete Operator
Move Operator...
Find Operator...
Edit Operator Data...
Update Certification...
Add Note...
Ready

Tab last updated: 11Sep2000 15:43

☐ Highlight Certification Status

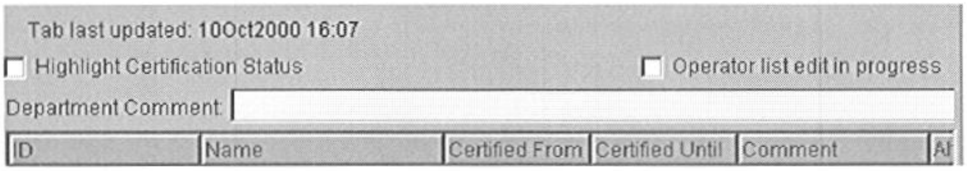
Department Comment:

Department	Method
Anesthesia	i-STAT
Anesthesia	PCx
Lab	i-STAT
Lab	PCx
Nursing	i-STAT
Nursing	PCx
Unassigned	i-STAT
Unassigned	PCx

ID	Name	Certified From	Certified Until	Comment
215647	David Smit	9/11/00	3/11/01	
221115	Mark West	9/11/00	3/11/01	
221518	Karen Stevens	10/10/00	4/10/01	
223655	Jane Brown	9/11/00	3/11/01	
224567	Mary Smith	9/11/00	3/11/01	
225478	John James	10/10/00	4/10/01	
225555	Ann O'Brien	9/11/00	3/11/01	
228991	Robert Dover	9/11/00	3/11/01	
229764	Sue Lent	9/11/00	3/11/01	
229798	Harrold Potter	10/10/00	4/10/01	
234556	Jane Little	9/11/00	3/11/01	

☐ Operator list edit in progress

When editing the operator list (Add Operator..., Delete Operator, etc.) check this box to delay updating the analyzers until all editing is complete. When editing is complete, click the box to remove the checkmark. This box will appear when Serial or Network Communications are enabled, Customization is enabled and Use Operator List is enabled.



Tab last updated: 10Oct2000 16:07

☐ Highlight Certification Status

☐ Operator list edit in progress

Department Comment:

ID	Name	Certified From	Certified Until	Comment	Al

☐ View Summary...

Summaries of operators can be viewed and printed by:

- This method and department only (department and method selected with ◄ symbol)
- This method, all departments (method selected with ◄ symbol)
- All methods, all departments

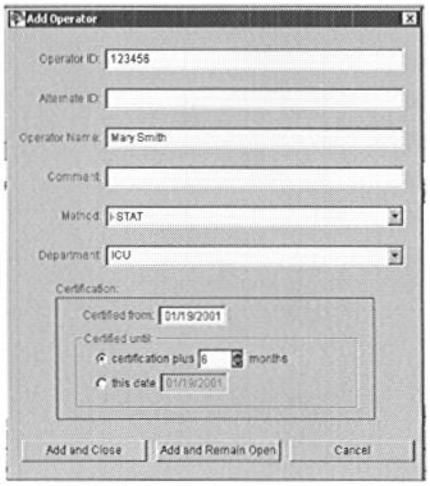
The reports include operator IDs, operator names, certified from date, certified until date, comments, a checkmark if certification has expired and the operator's alternate IDs grouped by department and method.

☐ Add Operator

This function is used to add new operators to the list of operators. Each operator must be added for each method for which the operator is certified.

In the case of the i-STAT 1 Analyzer, operators are certified separately for the i-STAT Cartridge method (i-STAT) and Precision PCx Glucose Test Strip method (Precision PCx).

To add the first operator to a Department, type the department name instead of selecting a department from the list of existing department. The new department will then be added to the list of existing departments.



Operator ID: 123456

Alternate ID:

Operator Name: Mary Smith

Comment:

Method: i-STAT

Department: ICU

Certification:

Certified from: 01/19/2001

Certified until:

● certification plus 6 months

○ this date 01/19/2001

☐ Delete Operator

Select the operator or operators and then click the **Delete Operator** button to delete the operator or operators. When the last operator from a department is deleted, the department disappears.

☐ Move Operator...

Select the operator or operators, click the **Move Operator...** button, and select a new department from the drop down list. If the department is not in the list, type in the new department name.

☐ Find Operator...

Click the **Find Operator...** button, select the method for which the operator is certified, and type in the operator ID. A box will appear around the found operator.

☐ Edit Department Name...

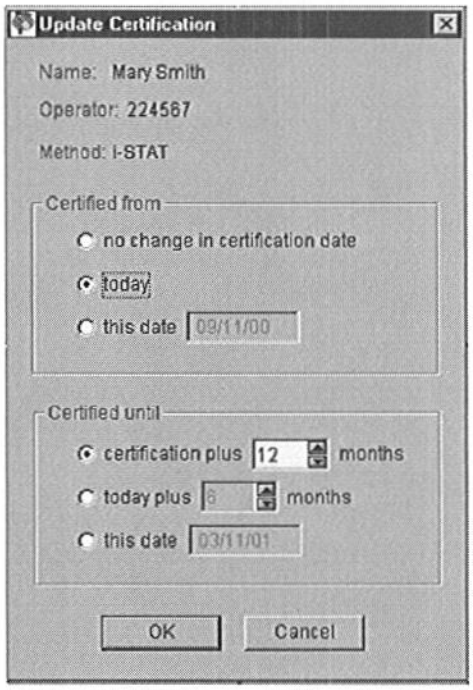
Click the department name to be changed and type in the new name. The Unassigned designation cannot be changed.

☐ Edit Operator Data...

Click the operator. The operator ID, name, comment and alternate ID can be edited.

☐ Update Certification...

Select the operator or operators and update the Certification form.



Update Certification

Name: Mary Smith

Operator: 224567

Method: I-STAT

Certified from

○ no change in certification date

● today

○ this date 09/11/00

Certified until

● certification plus 12 months

○ today plus 6 months

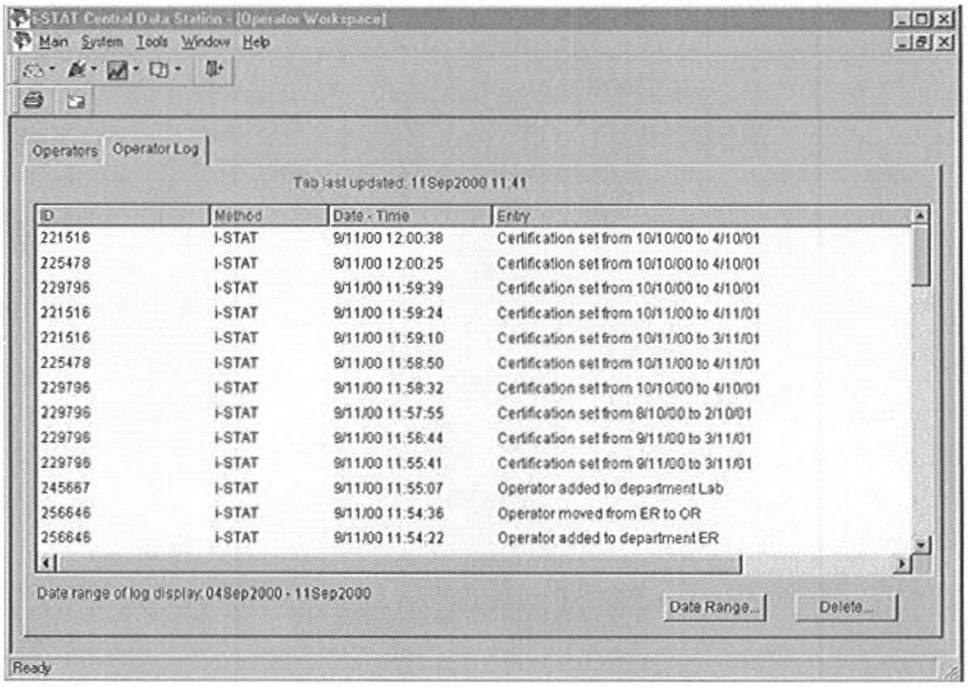
○ this date 03/11/01

☐ Add Note

Click the operator and then click the **Add Note...** button. An Operator Log Note of up to 50 characters can be typed.

Operator Log

The Operator Log tracks changes made and "Add Note" entries made in the Operator tab page. The **Date Range...** button can be used to specify a time period to be viewed and the **Delete...** button to delete entries. To print the log press the **F2** key or select **Print** from the Main menu.



i-STAT Central Data Station - [Operator Workspace]
Main System Tools Window Help
Operators
Operator Log

Tab last updated: 11Sep2000 11:41

ID	Method	Date - Time	Entry
221516	I-STAT	9/11/00 12:00:38	Certification set from 10/10/00 to 4/10/01
225478	I-STAT	9/11/00 12:00:25	Certification set from 10/10/00 to 4/10/01
229796	I-STAT	9/11/00 11:59:39	Certification set from 10/10/00 to 4/10/01
221516	I-STAT	9/11/00 11:59:24	Certification set from 10/11/00 to 4/11/01
221516	I-STAT	9/11/00 11:59:10	Certification set from 10/11/00 to 3/11/01
225478	I-STAT	9/11/00 11:58:50	Certification set from 10/11/00 to 4/11/01
229796	I-STAT	9/11/00 11:58:32	Certification set from 10/10/00 to 4/10/01
229796	I-STAT	9/11/00 11:57:55	Certification set from 8/10/00 to 2/10/01
229796	I-STAT	9/11/00 11:56:44	Certification set from 9/11/00 to 3/11/01
229796	I-STAT	9/11/00 11:55:41	Certification set from 9/11/00 to 3/11/01
245667	I-STAT	9/11/00 11:55:07	Operator added to department Lab
256646	I-STAT	9/11/00 11:54:36	Operator moved from ER to OR
256646	I-STAT	9/11/00 11:54:22	Operator added to department ER

Date range of log display: 04Sep2000 - 11Sep2000

DATABASE MAINTENANCE

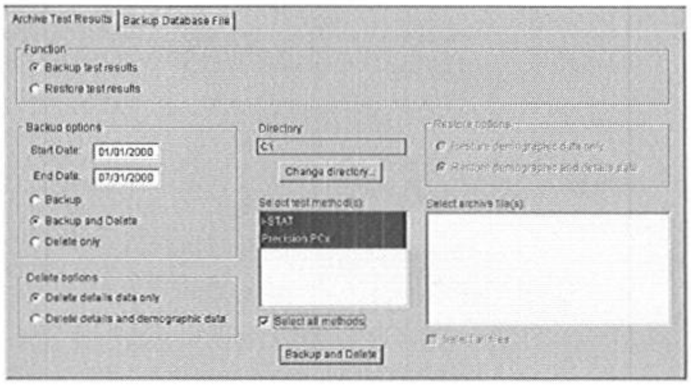
Overview

This workspace allows the database to be backed up, deleted and restored.

Archive Test Results

Backup test results: This function allows test results to be backed up onto a disk, CD or other directory. (Note: a 1.44MB disk will only store about 1000 test records.)

1. Click on **Main**, then **open Administration Functions**, then **Database Maintenance**.
2. After the workspace opens, click the **Archive Test Results** tab.
3. Click the **Backup test results** radio button.
4. Specify a date range for the function.
5. Select a **Backup Option**: **Backup**, **Backup and Delete**, or **Delete only.**
6. If an option that includes Delete is selected, then select a Delete Option: **Delete details data only** or **Delete details and demographic data.** (Demographic data can be used to generate reports.) Details data includes:
    - Original Operator and Patient ID
    - Patient Name
    - LIS order number
    - Sent status
    - Analyte values
    - Extra data
7. Select a Directory.
8. Select a method or methods to back up or click **Select all methods**.
9. Click the button marked **Backup** or **Backup and Delete** and follow the prompts.



Function
● Backup test results
○ Restore test results

Backup options
Start Date: 01/01/2000
End Date: 07/31/2000
○ Backup
● Backup and Delete
○ Delete only

Delete options
● Delete details data only
○ Delete details and demographic data

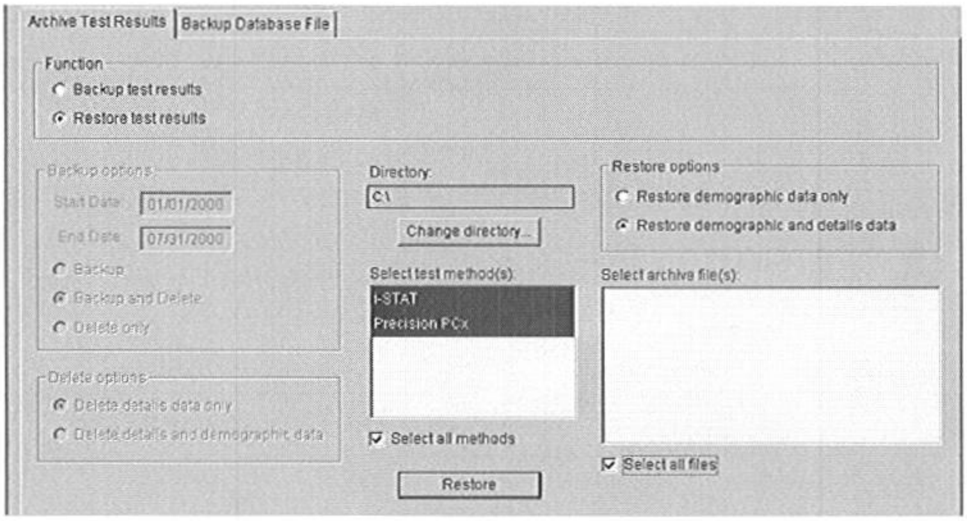
Directory: C:\

Select test method(s):
i-STAT
Precision PCx

☑ Select all methods

Restore test results: This function allows test results that have been deleted from the CDS but backed up elsewhere to be restored to the database.

1. Click on **Main**, then **open Administration Functions**, then **Database Maintenance**.
2. Insert disk or CD where files are located.
3. Click the **Restore test results** radio button.
4. Select the directory for the stored results.
5. Select the method or methods to be restored.
6. Select a restore option: **Restore demographic data only** or **Restore demographic and details data**. (Demographic data can be used to generate reports.)
7. Select the files to be restored or select all files.
8. Click the **Restore** button.



Archive Test Results | Backup Database File

Function
○ Backup test results
● Restore test results

Backup options
Start Date: 01/01/2000
End Date: 07/31/2000
○ Backup
● Backup and Delete
○ Delete only

Delete options
● Delete details data only
○ Delete details and demographic data

Directory: C:\

Restore options
○ Restore demographic data only
● Restore demographic and details data

Select test method(s):
i-STAT
Precision PCx

☑ Select all methods

Select archive file(s):

☑ Select all files

Backup Database File

This function allows the user to manually perform the same operation that occurs when the automatic database backup occurs. It creates a complete backup of the database file to the specified drive/directory.

CUSTOMIZATION WORKSPACE

This workspace is used to create profiles with site specific test characteristics for the analyzers.

Overview

See the Customization Worksheet at the end of this section for parameters that can be customized and the default settings.

Note: The default settings in the CDS software version 5 and above will override the settings in analyzers customized with the default settings from CDS software versions below 5.

Password

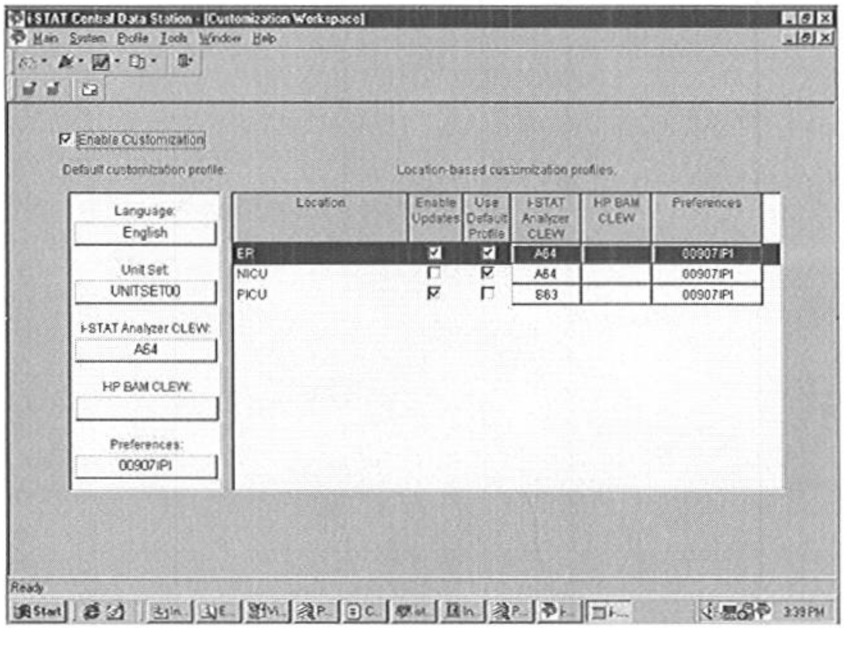
The Customization Workspace is password protected. The default password is **istat**. To change the password, select **Tools** and **Change Password** from the menu bar. A password from 3 to 8 characters can be used.

Enabling Customization

To enable customization, click the box to check it. When customization is enabled, the Central Data Station will check the Customization Profile for the location each time an analyzer is downloaded. If the location has the **Enable Updates** option checked, the Central Data Station will update the analyzer with the current Customization Profile for that location as noted below.

- Analyzers designated to **Report location as download location** in the Instrument workspace will be updated with the Customization Profile assigned to the download location, regardless of the location to which the instrument is assigned. Care should be taken when downloading instruments from locations other then their assigned location.
- Analyzers designated to **Always report location as this assignment** in the Instrument workspace will always be updated with the Customization Profile for the instrument's assigned location, regardless of the physical location from which it downloads.

If a location has the **Enable Updates** option unchecked, downloading from that location will result in no customization changes being made to analyzers designated to **Report location as download location.** Analyzers designated to **Always report location as this assignment** will not be updated if the assignment location for the instrument has the **Enable Updates** option unchecked, regardless of the setting associated with the physical location from which it downloads.


i-STAT Central Data Station - [Customization Workspace]
Main System Profile Tools Window Help
Ready

☑ Enable Customization

Default customization profile:

Language: English

Unit Set: UNITSET00

i-STAT Analyzer CLEW: A64

HP BAM CLEW:

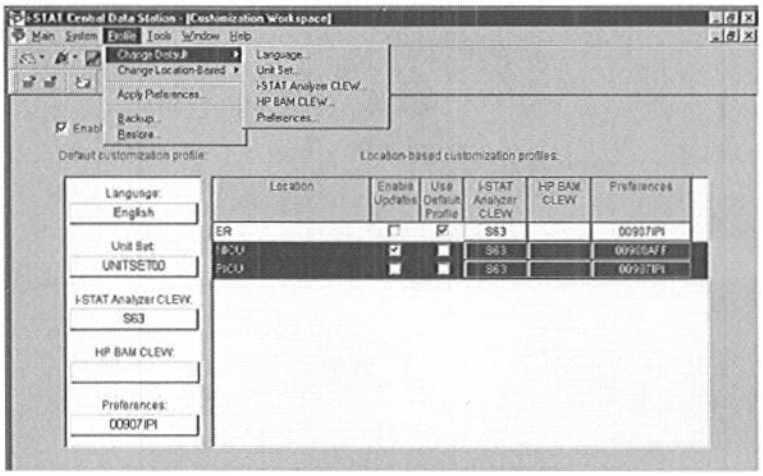
Preferences: 00907IPI

Location-based customization profiles:

Location	Enable Updates	Use Default Profile	i-STAT Analyzer CLEW	HP BAM CLEW	Preferences
ER	☑	☑	A64		00907IPI
NICU	☐	☑	A64		00907IPI
PICU	☑	☐	S63		00907IPI

Default Customization Profile

The first step in customization is to create a default customization profile. This is the profile initially assigned to every new location. To change the default profile, use the directions under Making Selections or click the menu option Profile, Change Default and the item to be changed. The changes in the default profile are automatically applied to every location using the default profile.


i-STAT Central Data Station - [Customization Workspace]
Main
System
Profile
Tools
Window
Help
Change Default
Change Location-Based
Apply Preferences...
Backup...
Restore...
Language...
Unit Set...
i-STAT Analyzer CLEW...
HP BAM CLEW...
Preferences...

☑ Enabl

Default customization profile:

Language: English

Unit Set: UNITSET00

i-STAT Analyzer CLEW: S63

HP BAM CLEW:

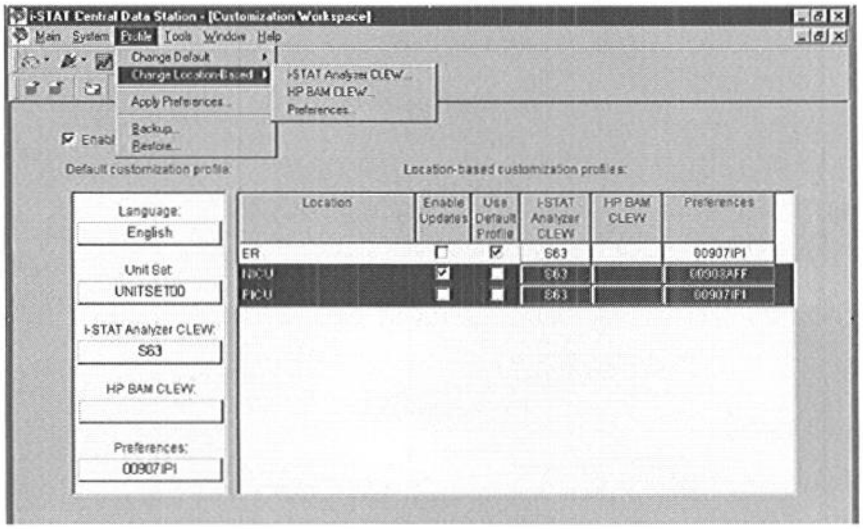
Preferences: 00907IPI

Location-based customization profiles:

Location	Enable Updates	Use Default Profile	i-STAT Analyzer CLEW	HP BAM CLEW	Preferences
ER	☐	☑	S63		00907IPI
NICU	☑	☐	S63		00908AFF
PICU	☐	☐	S63		00907IPI

Location-based Customization Profiles

Different customization profiles can be created for different locations. Uncheck the **Use Default Profile** box for the location and double click i-STAT Analyzer CLEW or HP BAM CLEW to change the CLEW or double click Preferences to change any of the preferences. Or, select the menu option Profile, Change Location-Based and the item to be changed. Changes in the customization profile can be made for several locations at once by selecting the locations and then selecting the appropriate option from the Profile Menu. If a location has the **Use Default Profile** option checked, its customization settings will not be changed even if it is selected. Note that Language and the Unit Set from the default customization profile are always used.


i-STAT Central Data Station - [Customization Workspace]
Main
System
Profile
Tools
Window
Help
Change Default
Change Location-Based
Apply Preferences...
Backup...
Restore...
i-STAT Analyzer CLEW...
HP BAM CLEW...
Preferences...

☑ Enabl

Default customization profile:

Language: English

Unit Set: UNITSET00

i-STAT Analyzer CLEW: S63

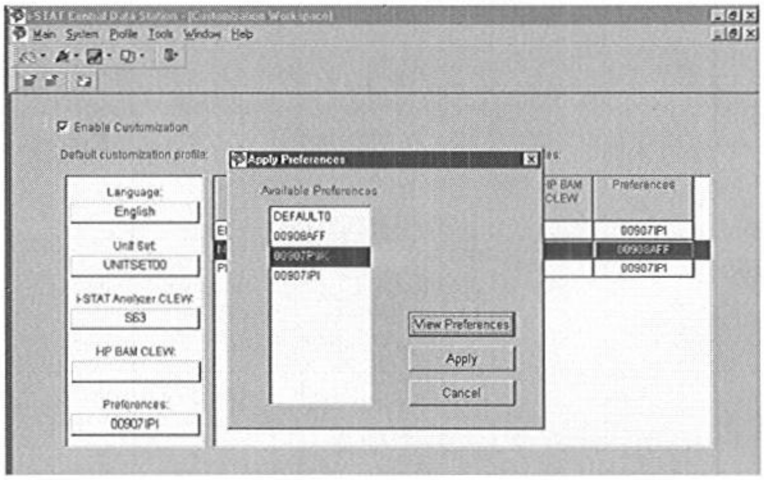
HP BAM CLEW:

Preferences: 00907IPI

Location-based customization profiles:

Location	Enable Updates	Use Default Profile	i-STAT Analyzer CLEW	HP BAM CLEW	Preferences
ER	☐	☑	S63		00907IPI
NICU	☑	☐	S63		00908AFF
PICU	☐	☐	S63		00907IPI

Preferences for locations can also be changed by selecting an existing preference from the Apply Preferences submenu. Select the location or locations to be changed. Click **Preferences**, then **Apply Preferences**, select the desired preferences and click **Apply**. Click **View Preferences** to review a set of preferences.


i-STAT Central Data Station - [Customization Workspace]
Main System Profile Tools Window Help
Apply Preferences
Available Preferences
DEFAULT0
00908AFF
00907P
00907IPI
View Preferences
Apply
Cancel
HP BAM CLEW
Preferences
00907IPI
00908AFF
00907IPI

☑ Enable Customization

Default customization profile:

Language: English

Unit Set: UNITSET00

i-STAT Analyzer CLEW: S63

HP BAM CLEW:

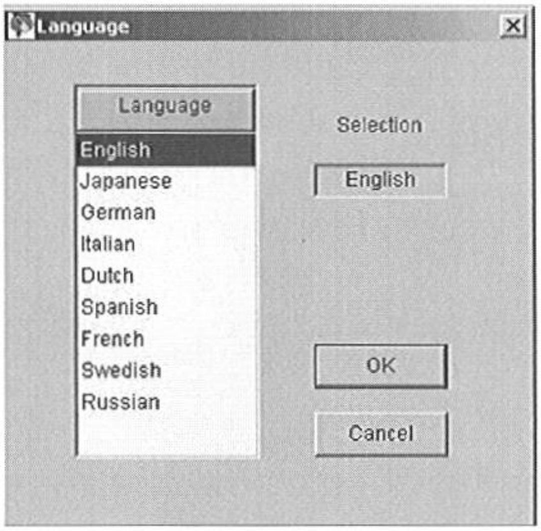
Preferences: 00907IPI

Making Selections

Selections are made from options in the following ways:

- Select one of the five main Customization options by double clicking the box for **Language, Unit Set, i-STAT Analyzer CLEW, HP BAM CLEW** or **Preferences.**
- After making a selection in the Language, Unit Set and CLEW window, click the **OK** button to save the selection or click the **Cancel** button to return to the previous selection.

Language Window

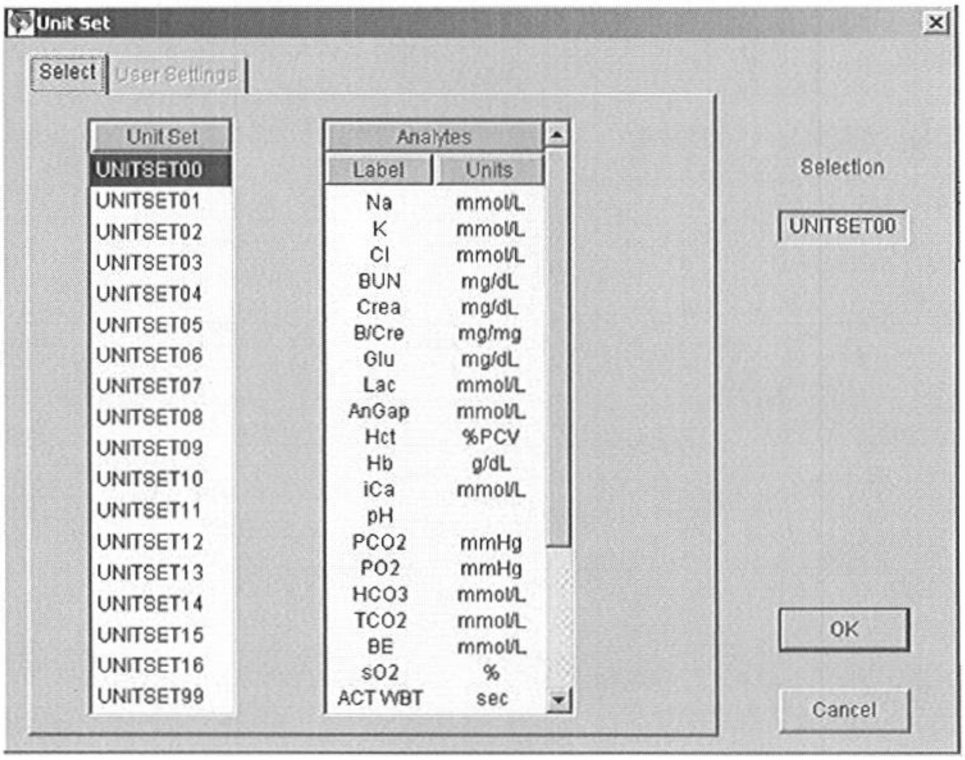

Language
Language
English
Japanese
German
Italian
Dutch
Spanish
French
Swedish
Russian
OK
Cancel

Selection: English

Note: Russian is available only on the i-STAT Portable Clinical Analyzer.

Unit Set Window

Details of each unit set are displayed under the Analytes column. Details are also listed in the Customization section in this manual.

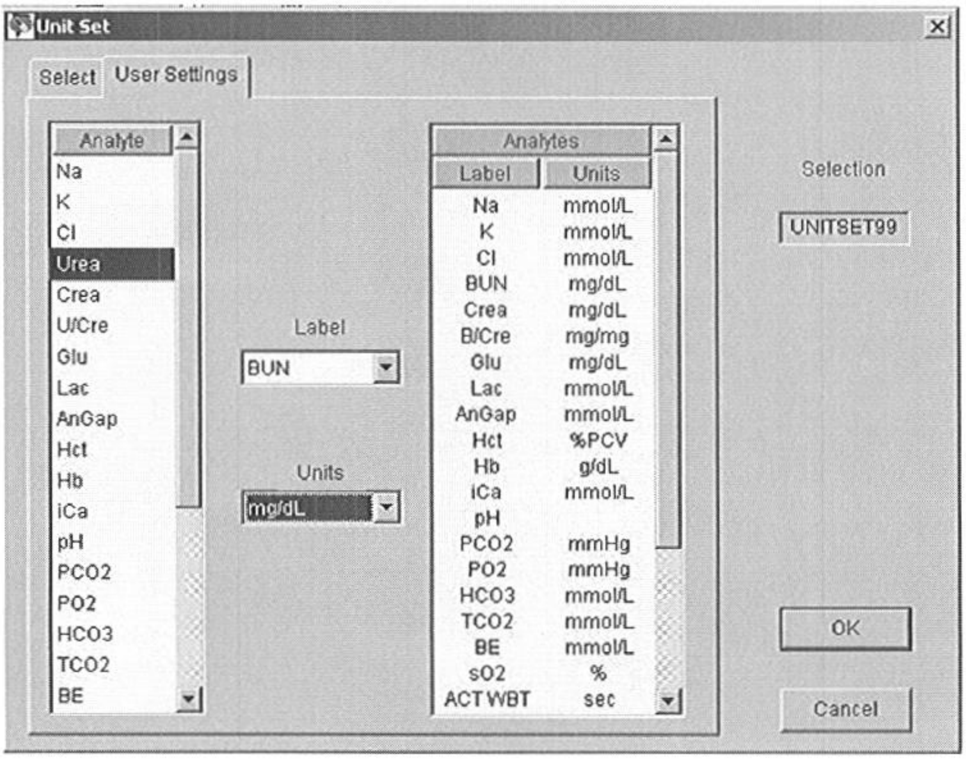

Unit Set
Select
User Settings
Unit Set
UNITSET00
UNITSET01
UNITSET02
UNITSET03
UNITSET04
UNITSET05
UNITSET06
UNITSET07
UNITSET08
UNITSET09
UNITSET10
UNITSET11
UNITSET12
UNITSET13
UNITSET14
UNITSET15
UNITSET16
UNITSET99
OK
Cancel

Analytes

Label	Units
Na	mmol/L
K	mmol/L
Cl	mmol/L
BUN	mg/dL
Crea	mg/dL
B/Cre	mg/mg
Glu	mg/dL
Lac	mmol/L
AnGap	mmol/L
Hct	%PCV
Hb	g/dL
iCa	mmol/L
pH	
PCO2	mmHg
PO2	mmHg
HCO3	mmol/L
TCO2	mmol/L
BE	mmol/L
sO2	%
ACT WBT	sec

Selection: UNITSET00

To create a unique unit set, click **UNITSET99** and then the **User Settings** tab. Then select the name and units for each analyte or test.


Unit Set
Select
User Settings
Analyte
Na
K
Cl
Urea
Crea
U/Cre
Glu
Lac
AnGap
Hct
Hb
iCa
pH
PCO2
PO2
HCO3
TCO2
BE
OK
Cancel

Label: BUN

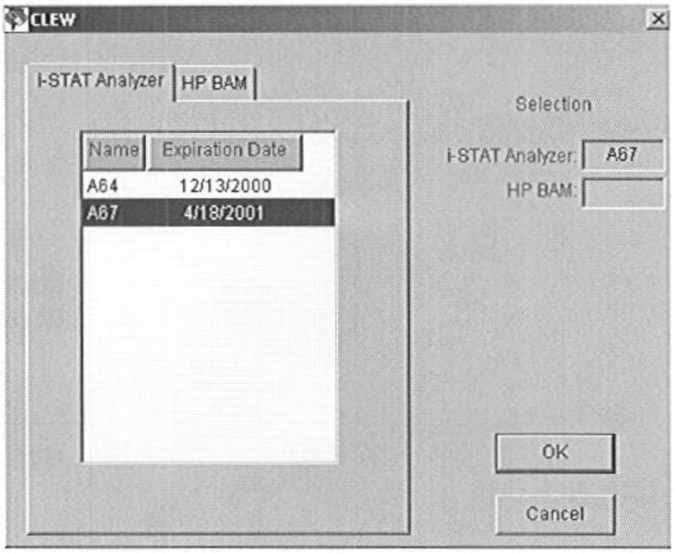
Units: mg/dL

Analytes

Label	Units
Na	mmol/L
K	mmol/L
Cl	mmol/L
BUN	mg/dL
Crea	mg/dL
B/Cre	mg/mg
Glu	mg/dL
Lac	mmol/L
AnGap	mmol/L
Hct	%PCV
Hb	g/dL
iCa	mmol/L
pH	
PCO2	mmHg
PO2	mmHg
HCO3	mmol/L
TCO2	mmol/L
BE	mmol/L
sO2	%
ACT WBT	sec

Selection: UNITSET99

CLEW Window



CLEW
i-STAT Analyzer
HP BAM
Selection
OK
Cancel

Name	Expiration Date
A64	12/13/2000
A67	4/18/2001

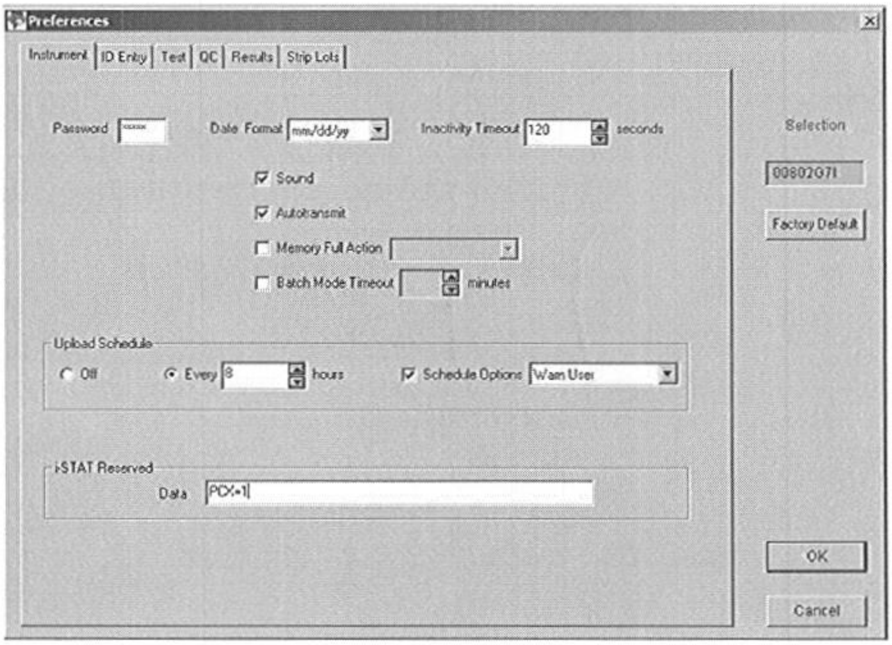
i-STAT Analyzer: A67

HP BAM:

A new CLEW is added to the window via the software update process three times a year. The Default customization profile must be updated after each new CLEW is added. Click the new CLEW and click OK. Note that there are separate CLEW for the i-STAT analyzers and the Agilent Blood Analysis Modules.

Note: Before changing to a new CLEW ensure that all analyzers have been updated to a compatible JAMS version.

Preferences Window



Preferences
Instrument
ID Entry
Test
QC
Results
Strip Lots
Selection
Factory Default
OK
Cancel

Password *****

Date Format mm/dd/yy

Inactivity Timeout 120 seconds

☑ Sound

☑ Autotransmit

☐ Memory Full Action

☐ Batch Mode Timeout minutes

Upload Schedule

○ Off ● Every 8 hours ☑ Schedule Options Warn User

i-STAT Reserved

Data PCX=1

Selection 00802071

The Preferences Window has six tab pages. Click the tab to display the desired page. The following conventions are used in the Preferences pages:

- Enable/disable an option by clicking the check box to check/uncheck it.
- Change a numeric setting by clicking and holding the ▲ or ▼ symbol or manually entering the number.

- Select an option from a list by clicking the ▼, and selecting the option from the list.
- Select from multiple options by clicking the radio button next to the desired option.
- Enter values into fields, such as for Reference Ranges and Strip Lot Numbers.

Note: To enable Precision PCx Glucose Test Strip testing on the i-STAT 1, type PCX=1 on the Data line in the i-STAT Reserved box. To disable glucose test strip testing, delete PCX=1 and leave the line blank.

When all information has been entered, a button is pressed:

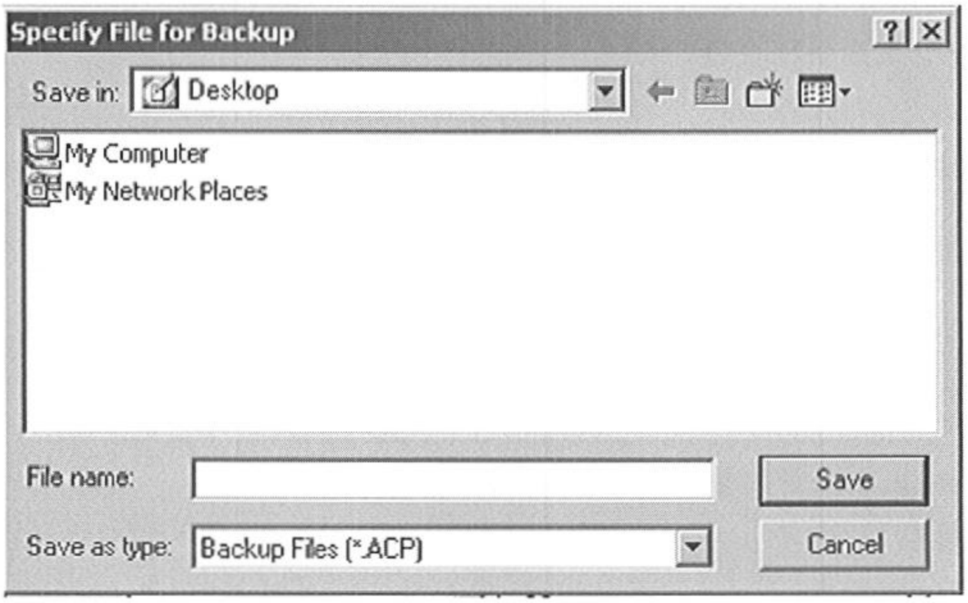
- **Factory Default** will restore the default settings to the open window.
- **OK** will store the new settings.
- **Cancel** will ignore any new settings and restore the current settings.

Each Customization Profile is assigned a unique name by the CDS program. This name appears under the Preferences column in the Customization Workspace window, on the Customization screen on the i-STAT 1 Analyzer, on the Analyzer Status screen on the i-STAT Portable Clinical Analyzer and on the Blood Analysis Setup screen of the Blood Analysis Module.

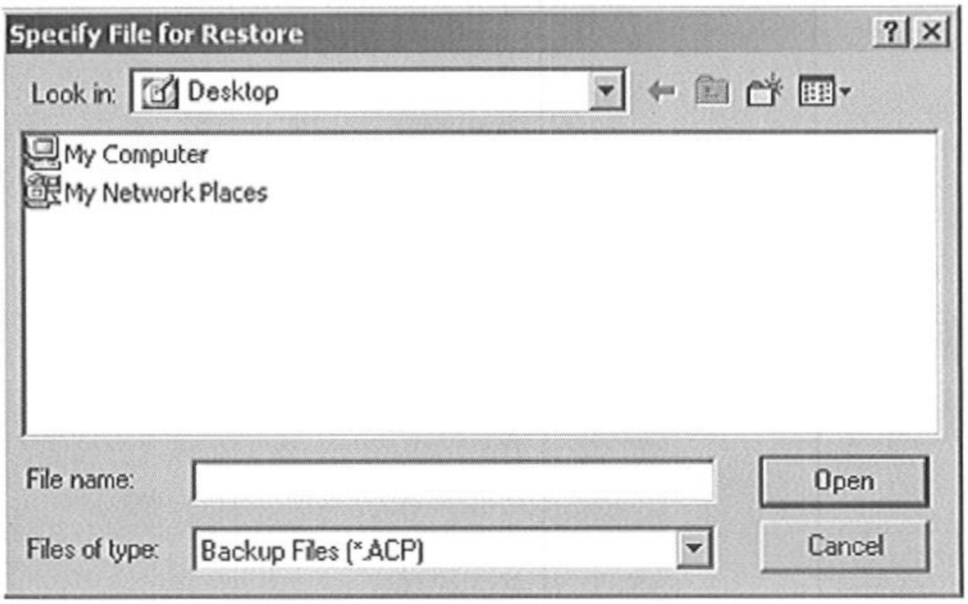
Caution: Close the Customization Workspace when finished to prevent inadvertent changes.

Backup and Restore Profile

The current customization profile can be stored by selecting **Profile**, then **Backup...** from the menu bar or by clicking the **Backup** toolbar button, selecting the directory where the profile is to be stored, typing in a file name for the profile, and clicking the **Save** button.



To restore a profile to the CDS, click **Profile** and then **Restore...** or the **Restore** toolbar button. Select the directory and backup file to restore and click the **Open** button.


Specify File for Restore
?
X
My Computer
My Network Places
Open
Cancel

Look in: Desktop

File name:

Files of type: Backup Files (*.ACP)

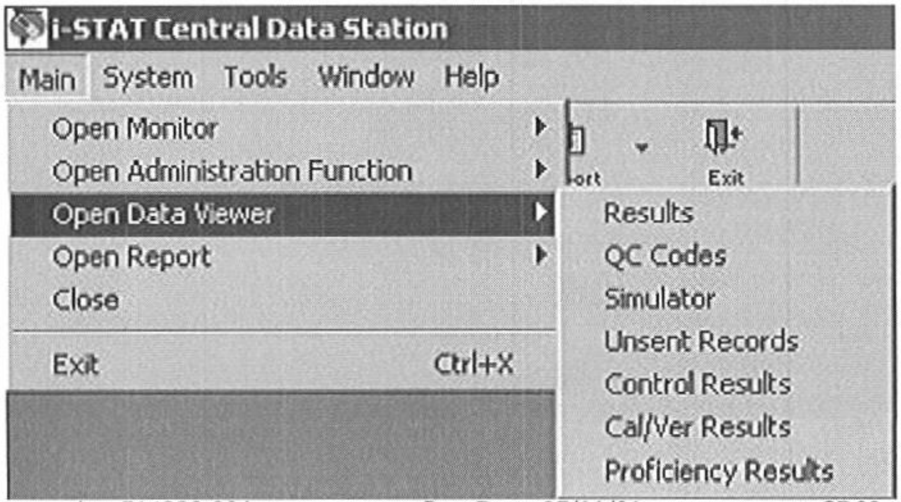
DATA VIEWERS

Overview

Data from instruments downloaded to the CDS are viewed in the Data Viewers.

Data downloaded from the i-STAT 1 Analyzers can be viewed in separate Data Viewers for Results, QC Codes, Simulator, Unsent Results, Control Results, Calibration Verification (or Linearity) Results and Proficiency Results (external quality control).

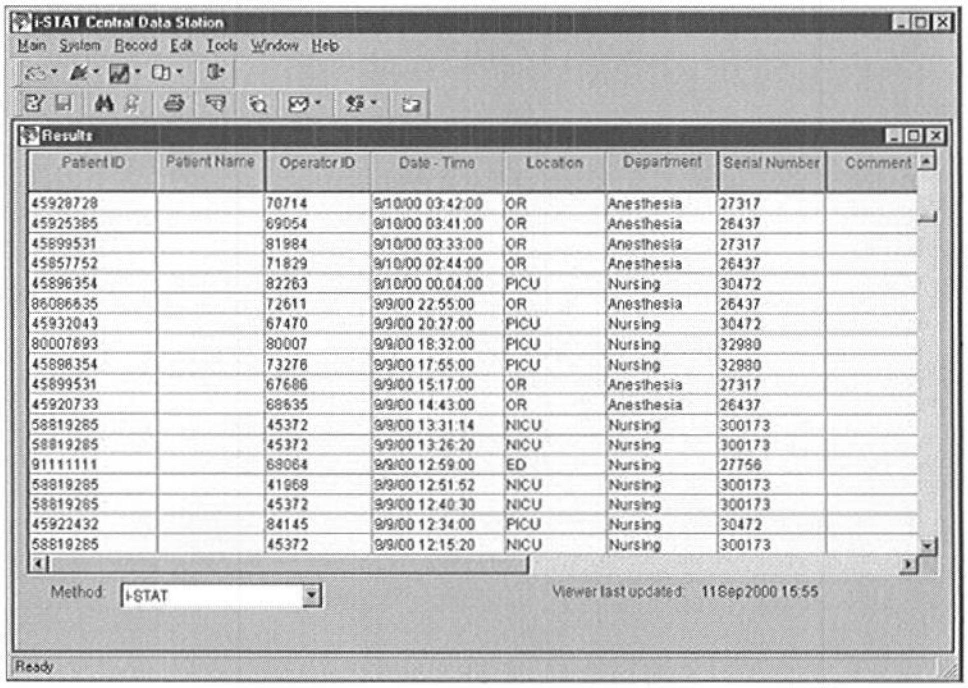
Control, Calibration Verification and Proficiency Results from the i-STAT Portable Clinical Analyzers and Agilent Blood Analysis Modules will appear in the Results Data Viewer.


i-STAT Central Data Station
Main
System
Tools
Window
Help
Open Monitor
Open Administration Function
Open Data Viewer
Open Report
Close
Exit Ctrl+X
ort
Exit
Results
QC Codes
Simulator
Unsent Records
Control Results
Cal/Ver Results
Proficiency Results

Information in Data Viewers

Data for only one method at a time, such as the i-STAT cartridges, is displayed in a viewer. To switch to a different method, select the method from the selection list in the lower left corner of the viewer. The exception is the Unsent Results Data Viewer which displays results from all methods. Records are listed based on which column is being sorted. Data can be displayed in ascending or descending order by clicking a column as described above.

Example: Results Data Viewer


i-STAT Central Data Station
Main System Record Edit Tools Window Help
Results

Patient ID	Patient Name	Operator ID	Date - Time	Location	Department	Serial Number	Comment
45928728		70714	9/10/00 03:42:00	OR	Anesthesia	27317	
45925385		69054	9/10/00 03:41:00	OR	Anesthesia	26437	
45899531		81984	9/10/00 03:33:00	OR	Anesthesia	27317	
45857752		71829	9/10/00 02:44:00	OR	Anesthesia	26437	
45896354		82263	9/10/00 00:04:00	PICU	Nursing	30472	
86086635		72611	9/9/00 22:55:00	OR	Anesthesia	26437	
45932043		67470	9/9/00 20:27:00	PICU	Nursing	30472	
80007693		80007	9/9/00 18:32:00	PICU	Nursing	32980	
45898354		73276	9/9/00 17:55:00	PICU	Nursing	32980	
45899531		67686	9/9/00 15:17:00	OR	Anesthesia	27317	
45920733		68635	9/9/00 14:43:00	OR	Anesthesia	26437	
58819285		45372	9/9/00 13:31:14	NICU	Nursing	300173	
58819285		45372	9/9/00 13:26:20	NICU	Nursing	300173	
91111111		68064	9/9/00 12:59:00	ED	Nursing	27756	
58819285		41968	9/9/00 12:51:52	NICU	Nursing	300173	
58819285		45372	9/9/00 12:40:30	NICU	Nursing	300173	
45922432		84145	9/9/00 12:34:00	PICU	Nursing	30472	
58819285		45372	9/9/00 12:15:20	NICU	Nursing	300173	

Method: i-STAT

Viewer last updated: 11Sep2000 15:55

Ready

Refreshing the Data

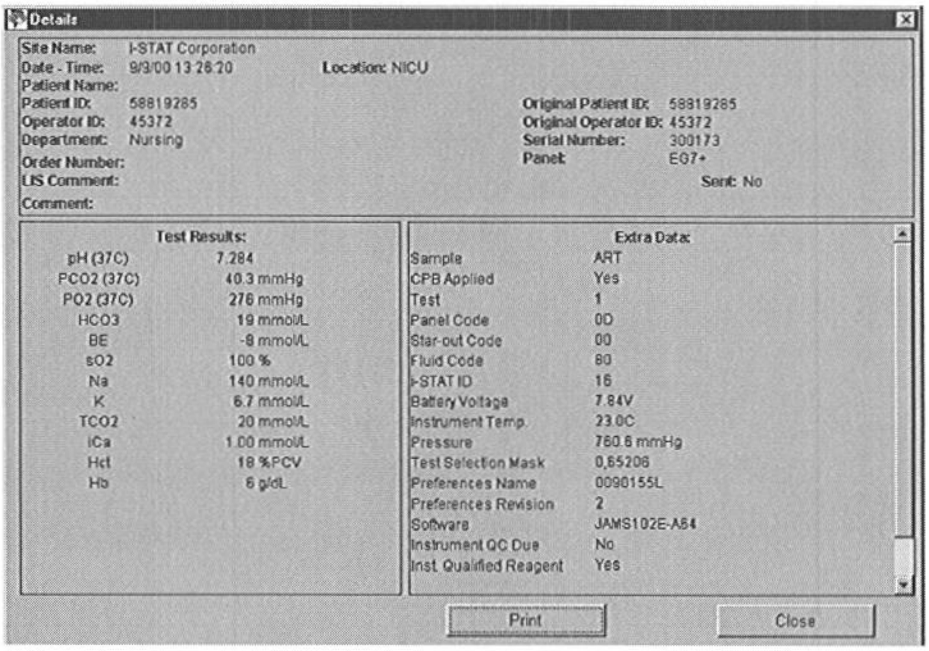
Data is received continuously by the CDS. Updating the viewers with the continuous incoming stream of data would make viewing the data difficult. Therefore, new data is not added to a viewer until the **Refresh** button is pressed. The window can also be refreshed by pressing **F5** or selecting **Refresh** from the **Window** option menu on the menu bar. The date and time of the latest refresh are listed on the bottom right of the window.

Viewing Details

The details of records in the Results, Control, Cal/Ver, Proficiency and Unsent Results Viewers can be viewed by double clicking the record or by selecting the record and clicking the **Details** toolbar button or by selecting **Record, View Details...** from the Menu.

Many of the Extra Data details may be helpful to the Customer Support representative in troubleshooting.

Example of Details for Results Viewer



Site Name: I-STAT Corporation
Date - Time: 9/3/00 13:28:20
Location: NICU
Patient Name:
Patient ID: 58819285
Operator ID: 45372
Department: Nursing
Order Number:
LIS Comment:
Comment:
Original Patient ID: 58819285
Original Operator ID: 45372
Serial Number: 300173
Panel: EG7+
Sent: No

Test Results:	
pH (37C)	7.284
PCO2 (37C)	40.3 mmHg
PO2 (37C)	276 mmHg
HCO3	19 mmol/L
BE	-8 mmol/L
sO2	100 %
Na	140 mmol/L
K	6.7 mmol/L
TCO2	20 mmol/L
iCa	1.00 mmol/L
Hct	18 %PCV
Hb	6 g/dL

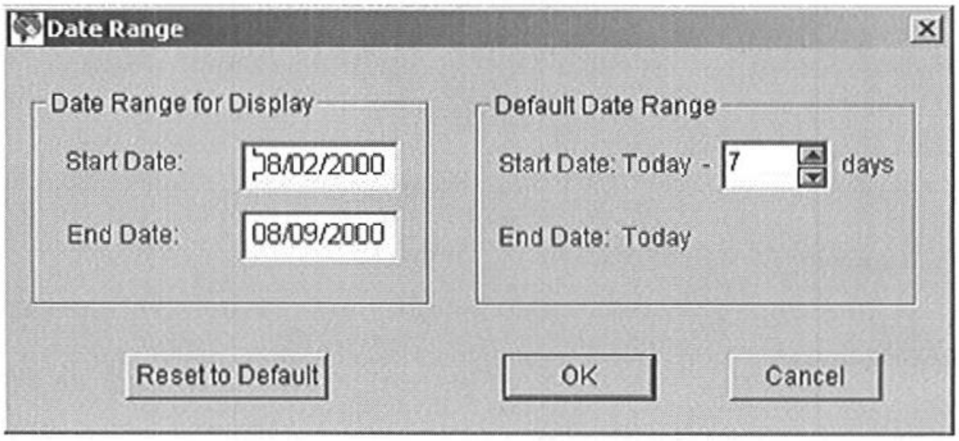
Extra Data:	
Sample	ART
CPB Applied	Yes
Test	1
Panel Code	0D
Star-out Code	00
Fluid Code	80
i-STAT ID	16
Battery Voltage	7.84V
Instrument Temp.	23.0C
Pressure	760.6 mmHg
Test Selection Mask	0,65206
Preferences Name	0090155L
Preferences Revision	2
Software	JAMS102E-A64
Instrument QC Due	No
Inst. Qualified Reagent	Yes

Customizing the Data Viewers

The viewers can be customized for individual preferences. The following aspects of the viewers are user configurable.

☐ **Selecting a Date Range**

The initial default date range for data in a viewer is the current date and back 7 days. The initial default range can be changed by selecting **Tools**, **Customize Viewer**, then **Date Range...** from the text menu, or by clicking the arrow next to the **Customize** toolbar button, then the **Date Range** button. A default date range can be set but overridden by entering a different date range for display. The maximum default date range allowed is 999 days.

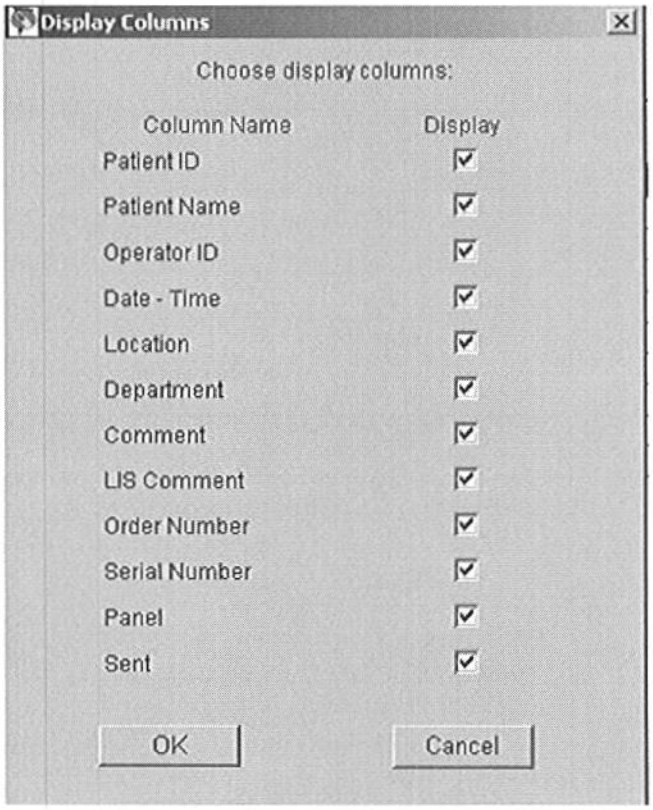


Start Date: 08/02/2000
End Date: 08/09/2000
Start Date: Today - 7 days
End Date: Today

The selection of a shorter date range enhances the system performance by limiting the amount of information needing to be presented. It is always possible to expand the range to view results from earlier and then reset to a more limited default period. The date range function only limits what is presented, not what is in the database.

☐ Selecting Columns to View

Columns can be hidden. Select **Tools**, **Customize Viewer**, then **Display Columns** or click the arrow next to the **Customize** toolbar button, then the **Columns** button. To hide a column, click the box following the column's name to uncheck it and then click **OK**. To make the column visible again, click the empty box following the column's name to check it and click the **OK** button.



Choose display columns:

Column Name	Display
Patient ID	☑
Patient Name	☑
Operator ID	☑
Date - Time	☑
Location	☑
Department	☑
Comment	☑
LIS Comment	☑
Order Number	☑
Serial Number	☑
Panel	☑
Sent	☑

Editing a Record

To edit a record, highlight the record to be edited, click **Record** then **Edit Record** in the menu bar or click the **Edit** toolbar button.

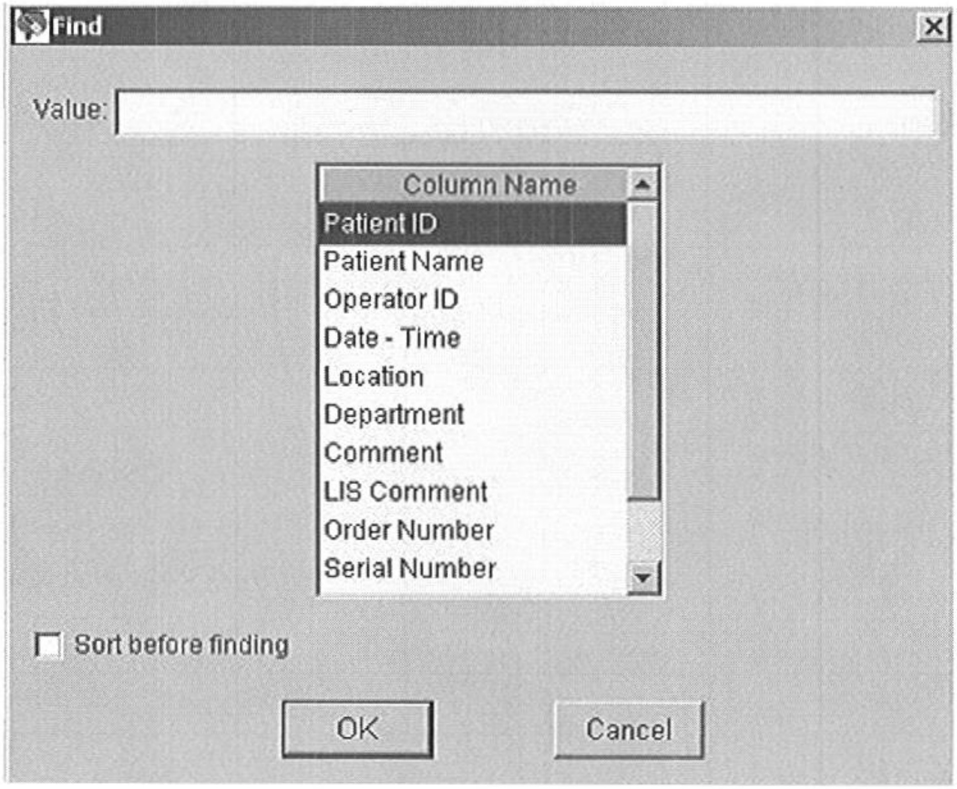
Different viewers have different editable items. Results that have been successfully sent to the LIS or HIS have only an editable Comment. Results marked as "Pending" or "In Progress" cannot be edited.

The Patient ID, Patient Name, Operator ID, Comment, LIS Comment and Order Number can be edited in the Results Viewer. Use the **Tab** key or the mouse to move across the line. The original Patient and Operator IDs will appear along with the edited IDs in the Details window.

Finding a Record

Different viewers have different lists from which to select for a search based on the data presented. Click **Record** and **Find** on the menu bar or click the **Find** toolbar button. Selecting **Sort before finding** before clicking OK will present the records in ascending order for the value after the first record matching the search is found.

Type on the Value line the desired parameter then highlight that parameter and click OK to find.


Find
Value:
Column Name
Patient ID
Patient Name
Operator ID
Date - Time
Location
Department
Comment
LIS Comment
Order Number
Serial Number
☐ Sort before finding
OK
Cancel

Printing Selected Records

With a Data Viewer open, highlight the records to be printed, click **Record** and **Print Selected Records** or click the **Print** toolbar button.

Send Selected Records

With a Data Viewer open, highlight the records to be sent, click **Record** and **Send Selected Records** or click the **Send** toolbar button.

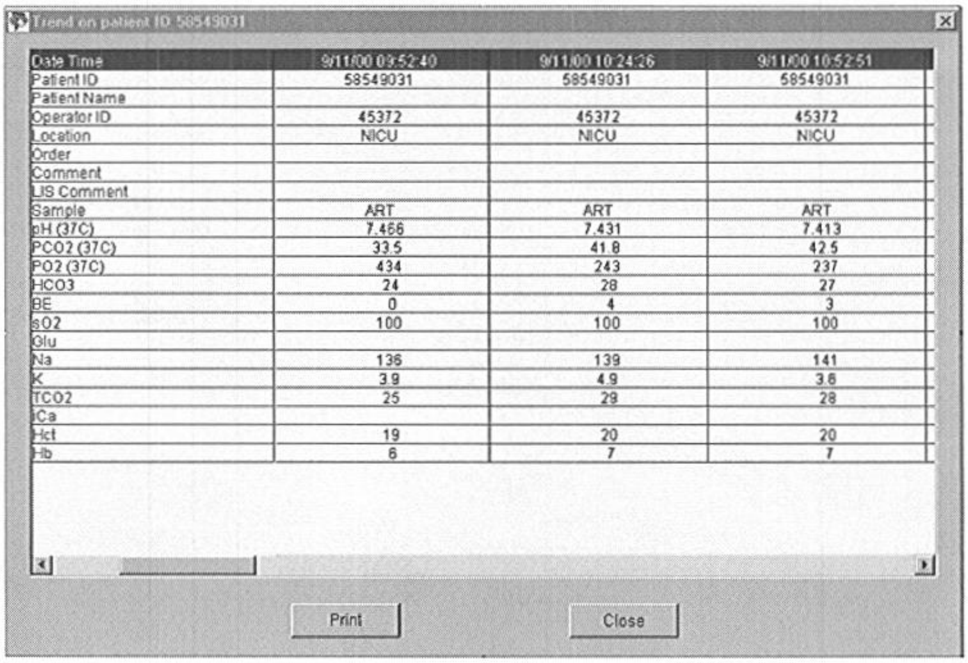
Trending Results

Results records in the Results, Control Results, Cal/Ver Results, Proficiency Results and Unsent Results Viewers can be selected for Trend reports. Trends can be performed on Patient ID, Control Lot Number, Calibration Verification Kit Number, Proficiency ID, Operator ID, Analyzer Serial Number or by a selection of records.

With the Data Viewer open, click **Record**, then **Trend**, then the trend option from the menu bar or click the arrow beside the **Trend** toolbar button and click the desired trend option. Up to 25 records are presented from oldest to newest data.

To trend by selection, highlight the records to be included in the trend report then perform the Trend function.

Example of a Result Trend by Patient ID



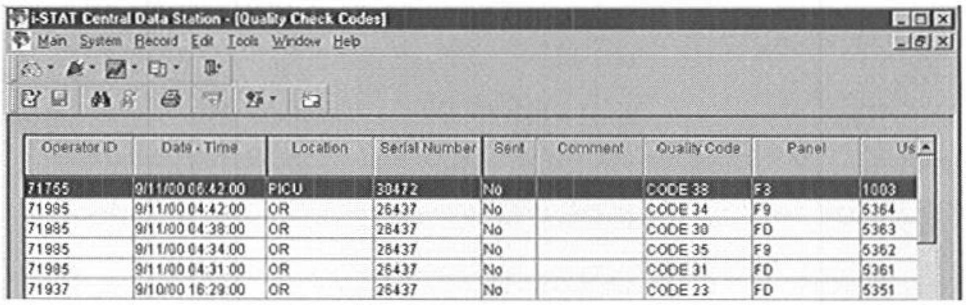
Trend on patient ID 58549031

Date Time	9/11/00 09:52:40	9/11/00 10:24:26	9/11/00 10:52:51
Patient ID	58549031	58549031	58549031
Patient Name			
Operator ID	45372	45372	45372
Location	NICU	NICU	NICU
Order			
Comment			
LIS Comment			
Sample	ART	ART	ART
pH (37C)	7.466	7.431	7.413
PCO2 (37C)	33.5	41.8	42.5
PO2 (37C)	434	243	237
HCO3	24	28	27
BE	0	4	3
sO2	100	100	100
Glu			
Na	136	139	141
K	3.9	4.9	3.6
TCO2	25	29	28
iCa			
Hct	19	20	20
Hb	6	7	7

QC Codes Viewer

All Quality Check Codes are listed in chronological order. To add a comment, click the record, then **Record**, then **Edit Record** on the menu bar or click the **Edit Record** toolbar button. To sort the Quality Check Codes by type, click the Quality Code column header. To list again in chronological order, click the Date-Time column header.

Note: Panel is a binary code for the cartridge types. To view the cartridge types associated with the Quality Check Codes, go to the Report functions.

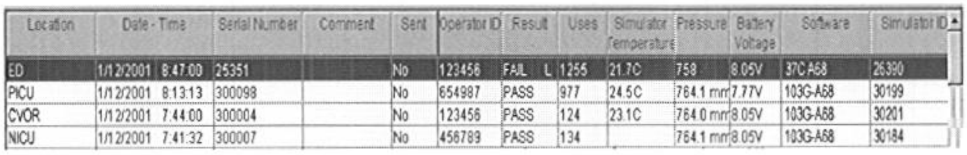


i-STAT Central Data Station - [Quality Check Codes]

Operator ID	Date - Time	Location	Serial Number	Sent	Comment	Quality Code	Panel	Us
71755	9/11/00 06:42:00	PICU	30472	No		CODE 38	F3	1003
71985	9/11/00 04:42:00	OR	26437	No		CODE 34	F9	5364
71985	9/11/00 04:38:00	OR	28437	No		CODE 30	FD	5363
71985	9/11/00 04:34:00	OR	26437	No		CODE 35	F9	5362
71985	9/11/00 04:31:00	OR	26437	No		CODE 31	FD	5361
71937	9/10/00 16:29:00	OR	26437	No		CODE 23	FD	5351

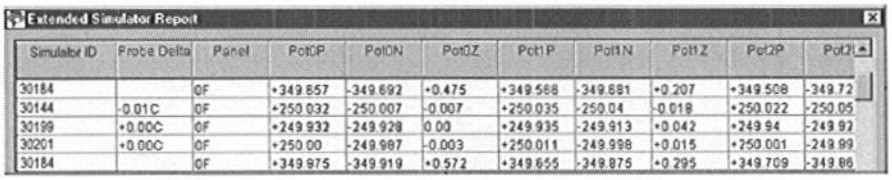
Electronic Simulator Viewer

All Electronic Simulator results, both external and internal, are listed in chronological order with the newest result at the top of the screen. To view all simulator results together for each analyzer, click the Serial Number column header to sort the analyzers by serial number or use the **Find** option and sort for one analyzer. To list in chronological order again, click the Date-Time header.



Location	Date - Time	Serial Number	Comment	Sent	Operator ID	Result	Uses	Simulator Temperature	Pressure	Battery Voltage	Software	Simulator ID
ED	1/12/2001 8:47:00	25351		No	123456	FAIL L	1255	21.7C	758	8.05V	37CA68	26390
PICU	1/12/2001 8:13:13	300098		No	654987	PASS	977	24.5C	764.1 mm	7.77V	103G-A68	30199
CVOR	1/12/2001 7:44:00	300004		No	123456	PASS	124	23.1C	764.0 mm	8.05V	103G-A68	30201
NICU	1/12/2001 7:41:32	300007		No	456789	PASS	134		764.1 mm	8.05V	103G-A68	30184

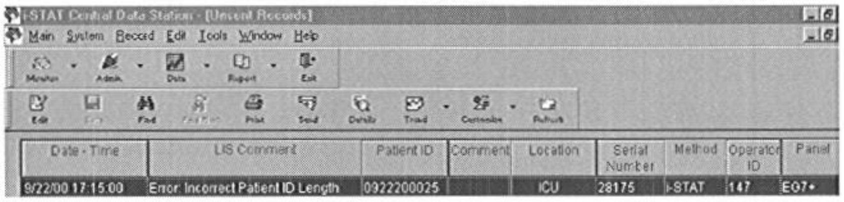
To view the thermal probe delta check and the actual readings taken during the Electronic Simulator check, click **Record**, then **View Extended Simulator Report**.



Simulator ID	Probe Delta	Panel	Pot0P	Pot0N	Pot0Z	Pot1P	Pot1N	Pot1Z	Pot2P	Pot2
30184		0F	+349.657	-349.692	+0.475	+349.568	-349.881	+0.207	+349.508	-349.72
30144	-0.01C	0F	+250.032	-250.007	-0.007	+250.035	-250.04	-0.018	+250.022	-250.05
30199	+0.00C	0F	+249.932	-249.928	0.00	+249.935	-249.913	+0.042	+249.94	-249.92
30201	+0.00C	0F	+250.00	-249.987	-0.003	+250.011	-249.998	+0.015	+250.001	-249.99
30184		0F	+349.975	-349.919	+0.572	+349.655	-349.875	+0.295	+349.709	-349.86

Unsent Records Viewer

This viewer is available only if the external interface is enabled in the Central Data Station Customization function. This data viewer displays records that have not been sent from the Central Data Station to an external computer system, such as an LIS. The incorrect information can be corrected using **Edit** and the corrected record resent.


i-STAT Central Data Station - [Unsent Records]
Main System Record Edit Tools Window Help
Monitor
Admin
Data
Report
Exit
Edit
Find
Print
Send
Details
Trend
Customize
Refresh

Date - Time	LIS Comment	Patient ID	Comment	Location	Serial Number	Method	Operator ID	Panel
9/22/00 17:15:00	Error: Incorrect Patient ID Length	0922200025		ICU	28175	i-STAT	147	EG7+

Unsent results can be removed from the viewer by highlighting the record and pressing the **F8** key or by selecting **Mark Selected Records as Sent** under the Record option on the menu bar.

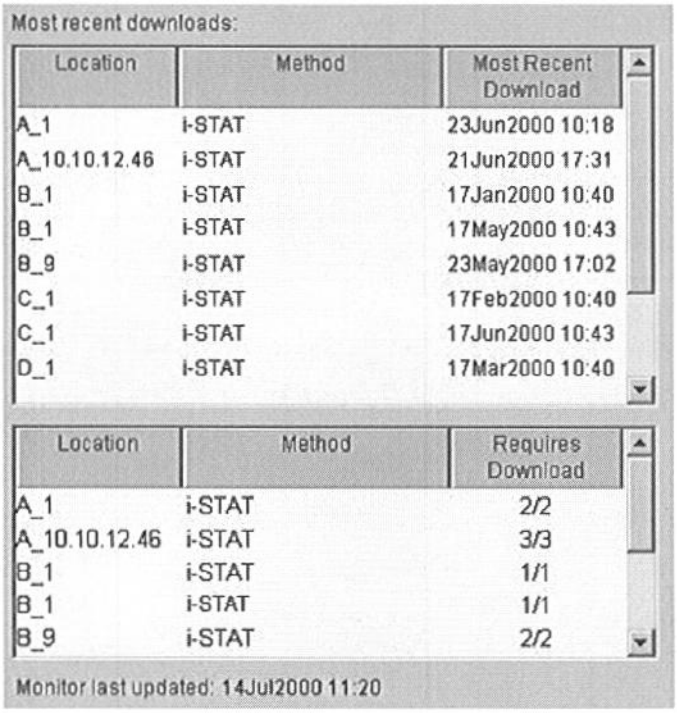
Download Monitor

The download monitor identifies quickly the download status of all locations and any locations that have instruments out of download compliance.

The upper portion of the monitor shows the last time an analyzer from the listed locations was downloaded. These columns can be sorted by clicking the column heading.

The maximum time allowed between downloads from the instrument to the CDS is defined under Download Criteria in the Instrument/Location workspace. The download status of each location is recorded in the Download Monitor. The Requires Download column indicates how many of the total number of analyzers reporting to a location have exceeded the Download Criteria. Clicking the location will open the Instrument and Location workspace where noncompliant analyzers will be highlighted.

The monitors are updated or refreshed according to the schedule selected during the customization of the CDS. The data can be manually refreshed by clicking the **Refresh** toolbar button or by pressing the **F5** key.



Most recent downloads:

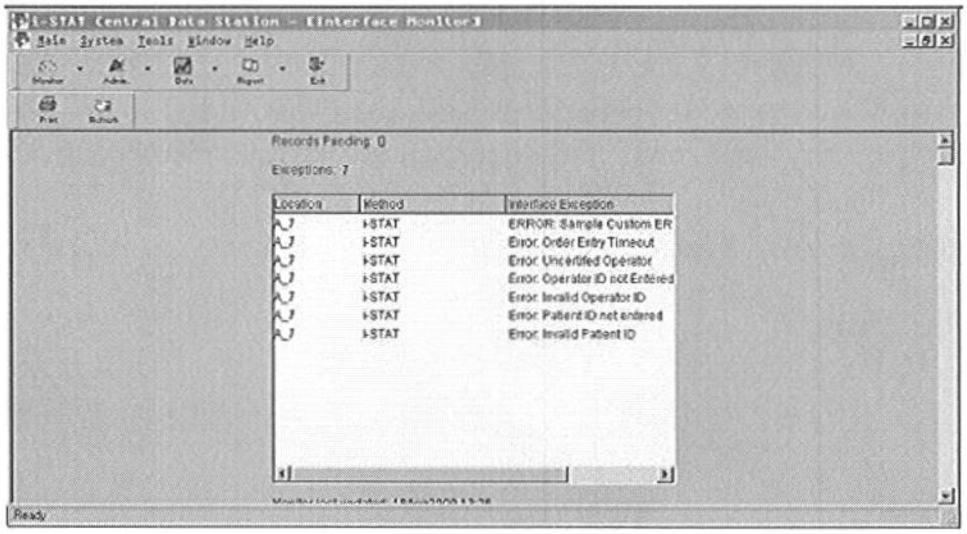
Location	Method	Most Recent Download
A_1	i-STAT	23Jun2000 10:18
A_10.10.12.46	i-STAT	21Jun2000 17:31
B_1	i-STAT	17Jan2000 10:40
B_1	i-STAT	17May2000 10:43
B_9	i-STAT	23May2000 17:02
C_1	i-STAT	17Feb2000 10:40
C_1	i-STAT	17Jun2000 10:43
D_1	i-STAT	17Mar2000 10:40

Location	Method	Requires Download
A_1	i-STAT	2/2
A_10.10.12.46	i-STAT	3/3
B_1	i-STAT	1/1
B_1	i-STAT	1/1
B_9	i-STAT	2/2

Monitor last updated: 14Jul2000 11:20

Interface Monitor

The Interface Monitor identifies quickly the status of the Interface to an external computer. The number of pending results is shown as well as any exceptions in the last 72 hours. Clicking an exception takes you to the Unsent Results viewer to address the exception.


i-STAT Central Data Station - [Interface Monitor]
Main System Tools Window Help
Monitor
Admin.
Data
Report
Exit
Print
Refresh
Ready

Records Pending: 0

Exceptions: 7

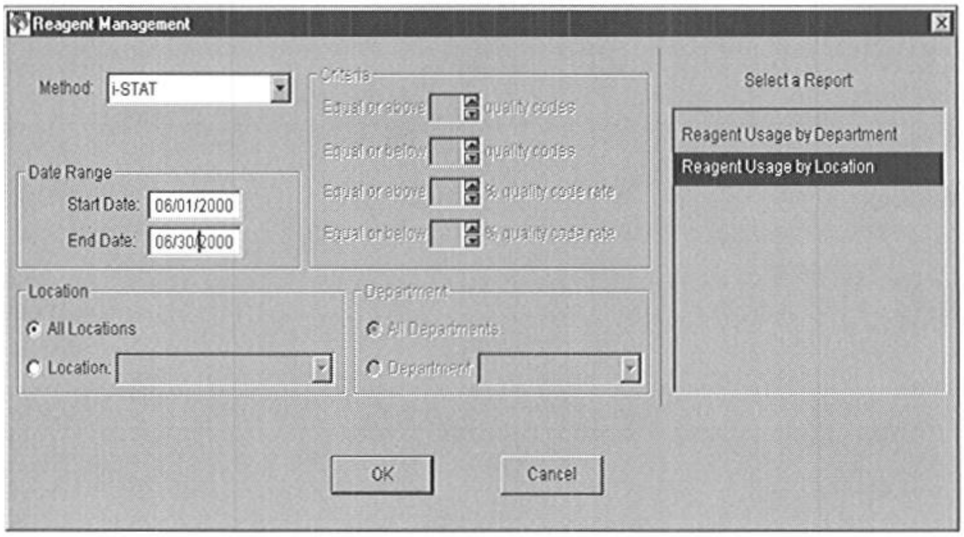
Location	Method	Interface Exception
A_J	i-STAT	ERROR: Sample Custom ER
A_J	i-STAT	Error: Order Entry Timeout
A_J	i-STAT	Error: Uncertified Operator
A_J	i-STAT	Error: Operator ID not Entered
A_J	i-STAT	Error: Invalid Operator ID
A_J	i-STAT	Error: Patient ID not entered
A_J	i-STAT	Error: Invalid Patient ID

Overview

Reports for managing the point-of-care testing process are available from the CDS program. Three reports can be generated: Reagent Management, Method Competency and Method Compliance. These show information summarized by operator, location or department. Reports can be printed.

Reagent Management

This is a report of cartridge usage by Department or Location. Select a date range for the report. Select a report by **Reagent Usage by Department** or **Reagent Usage by Location**, then select either **All Locations** or **All Departments**, or select one **Location** or one **Department** from the drop down menu. Then click the **OK** button.



Reagent Management

Method: i-STAT

Date Range

Start Date: 06/01/2000

End Date: 06/30/2000

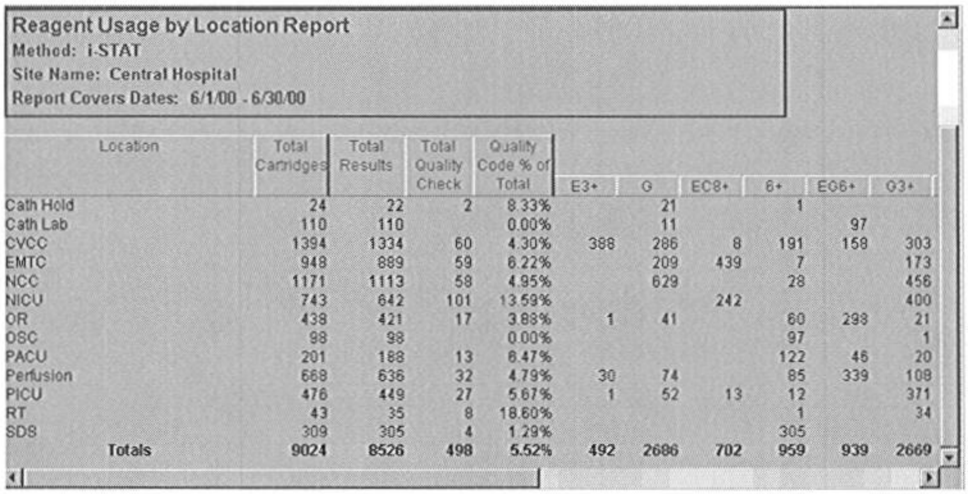
Location

● All Locations

○ Location:

Select a Report: Reagent Usage by Location

Criteria
Equal or above quality codes
Equal or below quality codes
Equal or above % quality code rate
Equal or below % quality code rate
Department
All Departments
Department
Reagent Usage by Department
OK
Cancel



Reagent Usage by Location Report

Method: i-STAT

Site Name: Central Hospital

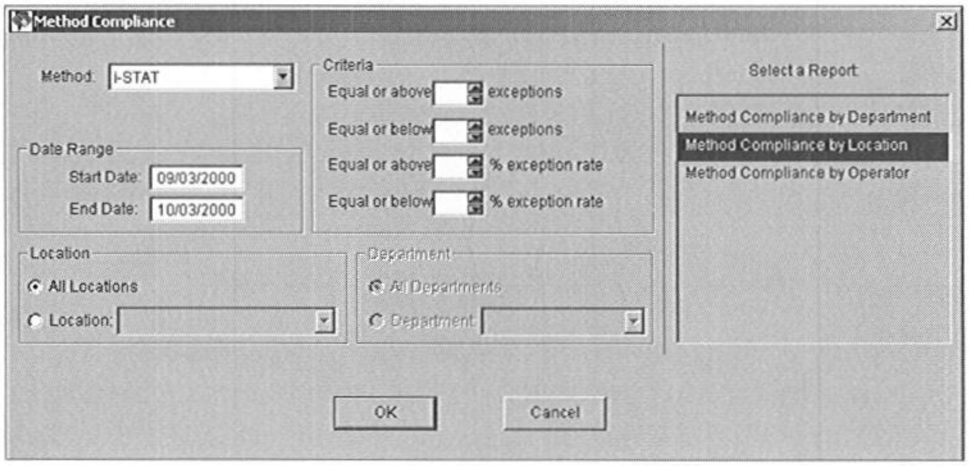
Report Covers Dates: 6/1/00 - 6/30/00

Location	Total Cartridges	Total Results	Total Quality Check	Quality Code % of Total	E3+	G	EC8+	6+	EG6+	G3+
Cath Hold	24	22	2	8.33%		21		1		
Cath Lab	110	110		0.00%		11			97	
CVCC	1394	1334	60	4.30%	388	286	8	191	158	303
EMTC	948	889	59	6.22%		209	439	7		173
NCC	1171	1113	58	4.95%		629		28		456
NICU	743	642	101	13.59%			242			400
OR	438	421	17	3.88%	1	41		60	298	21
OSC	98	98		0.00%				97		1
PACU	201	188	13	6.47%				122	46	20
Perfusion	668	636	32	4.79%	30	74		85	339	108
PICU	476	449	27	5.67%	1	52	13	12		371
RT	43	35	8	18.60%				1		34
SDS	309	305	4	1.29%				305		
Totals	**9024**	**8526**	**498**	**5.52%**	**492**	**2686**	**702**	**959**	**939**	**2669**

Method Compliance

This is a report of exceptions of policy and procedure for cartridge testing by Department, Location or Operator. This information is available when there is an interface to an external computer.

Select a date range for the report. Select a **Report by Department**, **Location** or **Operator**, then select **All Locations** or **All Departments** or select one **Location** or **Department** from the drop down menu. Select the filtering criteria for the report. Then click the **OK** button.



Method Compliance

Method: i-STAT

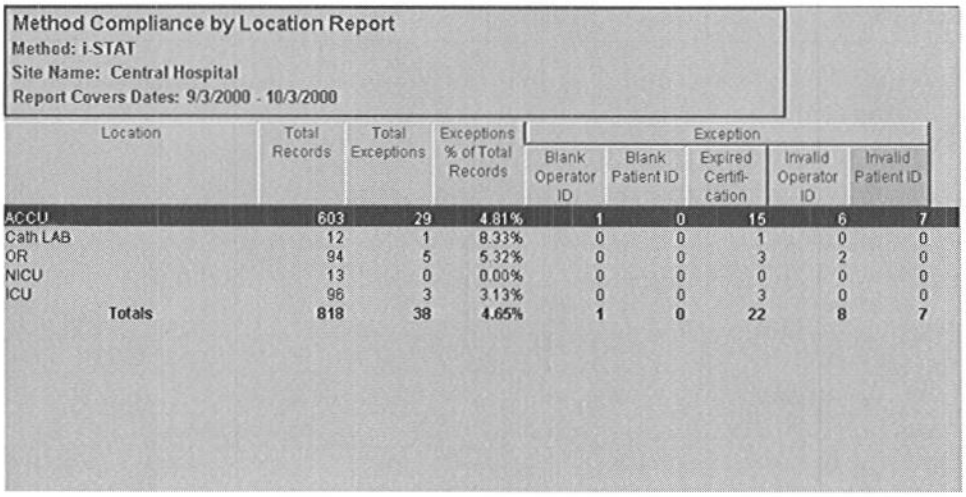
Criteria
Equal or above ☐ exceptions
Equal or below ☐ exceptions
Equal or above ☐ % exception rate
Equal or below ☐ % exception rate

Date Range
Start Date: 09/03/2000
End Date: 10/03/2000

Location
● All Locations
○ Location:

Department
● All Departments
○ Department:

Select a Report
Method Compliance by Department
Method Compliance by Location
Method Compliance by Operator

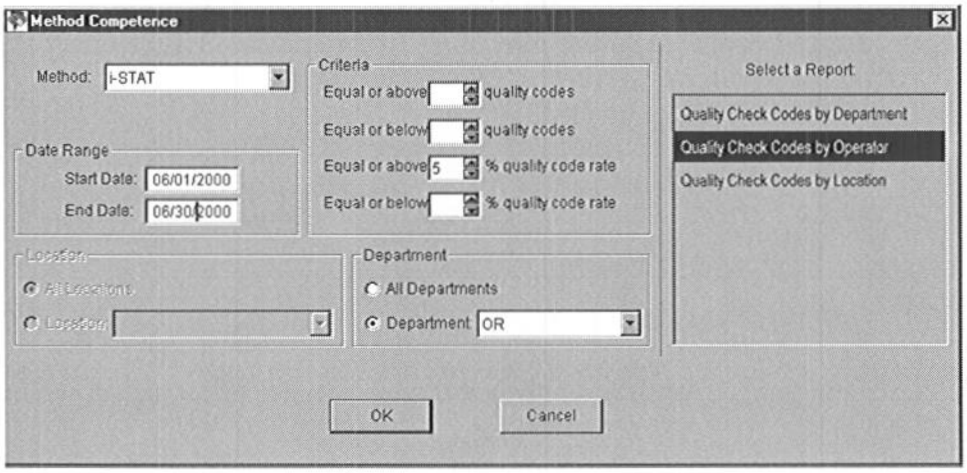


Method Compliance by Location Report
Method: i-STAT
Site Name: Central Hospital
Report Covers Dates: 9/3/2000 - 10/3/2000

Location	Total Records	Total Exceptions	Exceptions % of Total Records	Exception				
				Blank Operator ID	Blank Patient ID	Expired Certification	Invalid Operator ID	Invalid Patient ID
ACCU	603	29	4.81%	1	0	15	6	7
Cath LAB	12	1	8.33%	0	0	1	0	0
OR	94	5	5.32%	0	0	3	2	0
NICU	13	0	0.00%	0	0	0	0	0
ICU	96	3	3.13%	0	0	3	0	0
Totals	**818**	**38**	**4.65%**	**1**	**0**	**22**	**8**	**7**

Method Competence This is a report of Quality Check Code occurrence for cartridges by Department, Location or Operator.

Select a date range for the report. Select a **Report by Department**, **Location** or **Operator**, then select **All Locations** or **All Departments** or select one **Location** or **Department** from the drop down menu. Select the filtering criteria for the report. Then click the **OK** button.



Method Competence

Method: i-STAT

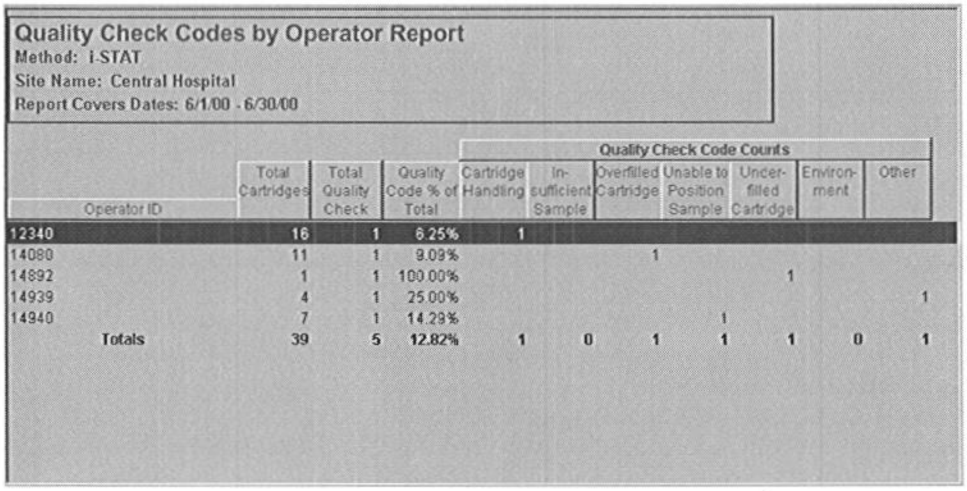
Date Range
Start Date: 06/01/2000
End Date: 06/30/2000

Criteria
Equal or above ☐ quality codes
Equal or below ☐ quality codes
Equal or above 5 % quality code rate
Equal or below ☐ % quality code rate

Location
● All Locations
○ Location

Department
○ All Departments
● Department: OR

Select a Report
Quality Check Codes by Department
Quality Check Codes by Operator
Quality Check Codes by Location



Quality Check Codes by Operator Report
Method: i-STAT
Site Name: Central Hospital
Report Covers Dates: 6/1/00 - 6/30/00

				Quality Check Code Counts						
Operator ID	Total Cartridges	Total Quality Check	Quality Code % of Total	Cartridge Handling	In-sufficient Sample	Overfilled Cartridge	Unable to Position Sample	Under-filled Cartridge	Environ-ment	Other
12340	16	1	6.25%	1						
14080	11	1	9.09%			1				
14892	1	1	100.00%					1		
14939	4	1	25.00%							1
14940	7	1	14.29%				1			
Totals	**39**	**5**	**12.82%**	**1**	**0**	**1**	**1**	**1**	**0**	**1**

SYSTEM

Customization: Central Data Station Settings	Configuration of the CDS can be viewed.
Customization: i-STAT Analyzer Settings	Customization profiles of the i-STAT analyzers can be viewed.
AutoSend	When enabled, data will be transmitted automatically from the CDS to the LIS or other information management system when received by the CDS. If AutoSend is not enabled, results can be sent to the LIS manually. Highlight the records to be sent in the appropriate Data Viewer Results viewer then click **Record** and **Send Selected Records**. If AutoSend is enabled, it will be checkmarked under the System option on the menu bar. If an external interface is not enabled, AutoSend will appear in grey typeface.

HELP

Technical Support	Phone number for your Customer Support Representative.
About...	Software version of the Central Data Station.

i-STAT ANALYZER CUSTOMIZATION

INSTRUMENT OPTIONS

Option	Description	Choices i-STAT1	Choices Port. Clin. An. & BAM	Default0	New Default	Loc:_______	Loc:_______	Loc:_______
Password	For Clock Set, Change customization, and Utility functions protection.	0-5 digits	N/A	No password				
Date Format	For Clock Set function	mm/dd/yy dd/mm/yy	N/A	mm/dd/yy				
Inactivity Timeout	Number of seconds after results are displayed and there is no operator intervention that analyzer will turn off	45 to 1620 seconds	N/A	120 seconds				
Sound	Optional beep when results or Quality Check are displayed	Enabled or Disabled	N/A	Enabled				
Auto Transmit	Analyzer automatically transmits results when placed in a downloader	Enabled or Disabled	N/A	Enabled				
Memory Full Action	What will happen when analyzer's memory contains 5000 unsent results	Disabled: results are over-written without warning. Enabled: Warn or Lock Out	N/A	Disabled				
Batch Mode Timeout	Not active at this time		N/A					
Upload Schedule	Time interval between uploads from analyzer to CDS. Schedule Options if time interval exceeded.	Off or specified time interval in hours from 1 to 65535 Warn Lock Out	N/A	Off				
Enable PCx Glucose	Enables the PCx glucose test strip reader on the i-STAT 1 Analyzer	Not enabled	N/A	Not enabled				
Printing	Customize the analyzer to receive data from either a protocol or non-protocol printer	Non-protocol	N/A	Not enabled				

OPERATOR AND PATIENT IDs

Option	Description	Choicesi-STAT1	ChoicesPort. Clin. An. & BAM	Default0	New Default	Loc:_______	Loc:_______	Loc:_______
Operator ID	Minimum and maximum allowed ID length	Minimum = 0 Maximum = 15	Minimum = 0 Maximum = 7	Minimum = 0 Maximum = 15				
Repeat ID Entry	Analyzer can prompt for repeat entry of operator ID	Enabled Disabled	Enabled Disabled	Enabled				
Barcode Option for Operator	Five barcodes are recognized by the analyzer	Enable or disable each barcode type. See Barcode Table.	N/A	All barcode types enabled				
Use Operator List	The certified operator list from the CDS is downloaded to the analyzers.	Enabled Disabled	N/A	Disabled				
Operator Not Certified Action	What the analyzer will do if operator not certified.	Disabled Enabled as Warn or Enabled as Lock Out	N/A	Disabled				
Patient ID	Minimum and maximum allowed ID length	Minimum = 0 Maximum = 15	Minimum = 0 Maximum = 12	Minimum = 0 Maximum = 15				
Repeat ID Entry	Analyzer can prompt for repeat entry	Enabled Disabled	Enabled Disabled	Enabled				
Patient ID Recall	Operator can recall last patient ID when analyzer prompts for patient ID	Enabled Disabled	Enabled Disabled	Enabled				
Barcode Options for Patient	Five barcodes are recognized by the analyzer	Enable or disable each barcode type. See Barcode Table.	N/A	All barcode types enabled				

BAR CODES

OPTION	DESCRIPTION	DEFAULT
ID Barcodes	The user can select any or all of the following as valid barcode formats for both the operator and patient ID: • I2 of 5 • Code128 • Codabar • Code93 • Code39	All
I2 of 5 Options	1. No Check Digit 2. USS Check Digit 3. OPCC Check Digit	USS Check Digit
Code 39 Options	1. Check Digit or No Check Digit 2. Alphanumeric or Full ASCII	Check Digit, Full ASCII
Truncate Digits	User can select how to truncate digits from a scanned operator and/or patient ID: First: enter number of leading characters to be stripped from the barcode. Last: enter number of trailing characters to be stripped from the barcode.	No truncation

Option	Description	Choices i-STAT1	Choices Port. Clin. An. & BAM	Default0	New Default	Loc:______	Loc:______	Loc:______
Auto-Chart Presentation	If enabled, the Chart page is displayed automatically.	Enabled Disabled	Enabled Disabled	Disabled				
Cartridge Patient Test	If "Required information before running cartridge" is enabled, the operator must enter the operator and patient IDs before the analyzer will initiate a cartridge test cycle. If "Enter Lot Number" is enabled, the cartridge lot number must be entered before the analyzer will initiate a cartridge test cycle.	Enabled Disabled	N/A	Disabled				
Patient Test Comment Code	If enabled, the analyzer will prompt for a 1 to 3 character comment code after results for patient samples are displayed.	If "Prompt for Comment Code, All Results in Range" and/or "Prompt for Comment Code, Any Result is out of Range" is enabled, an action of either "Allow no Comment" i.e., comment code optional, or "Require Comment" is selected.	N/A	Disabled	☐ Prompt all results in range ☐ Optional ☐ Required ☐ Prompt Result out of range ☐ Optional ☐ Required	☐ Prompt all results in range ☐ Optional ☐ Required ☐ Prompt Result out of range ☐ Optional ☐ Required	☐ Prompt all results in range ☐ Optional ☐ Required ☐ Prompt Result out of range ☐ Optional ☐ Required	☐ Prompt all results in range ☐ Optional ☐ Required ☐ Prompt Result out of range ☐ Optional ☐ Required
Sample Types for Cartridges	Drop Down means for each of the six sample types allows the sample types to be re-ordered or changed using up to 4 characters.	User selected from drop down menus.	1 ART 2 VEN 3 CAP 4 CORD 5 MXVN 6 CPB	1 ART 2 VEN 3 MIX 4 CAP 5 CORD 6 OTHR				
Test Strip Prompt for Sample Type	How the operator will record the sample type.	Prompt to choose between Art/Cap and Ven. Art/Cap always Ven always	N/A	Prompt	☐ Prompt for sample ☐ ART/CAP always ☐ VEN always	☐ Prompt for sample ☐ ART/CAP always ☐ VEN always	☐ Prompt for sample ☐ ART/CAP always ☐ VEN always	☐ Prompt for sample ☐ ART/CAP always ☐ VEN always

Option	Description	Choices i-STAT1	Choices Port. Clin. An. & BAM	Default0	New Default	Loc:_______	Loc:_______	Loc:_______
External Simulator Schedule	Time interval when a prompt for operator to use the external simulator should appear. The behavior of analyzer if the schedule is not met can also be specified. Schedule Options are Warn (start-up warning) and Lockout (disable cartridge testing until simulator used).	Off (no prompt) Interval of specified hours (1 to 65535 hours). Warn or Lock-out	Off Interval of specified hours. Warn	Off	☐ Off ☐ Every__hours ☐ Warn ☐ Lock Out	☐ Off ☐ Every__hours ☐ Warn ☐ Lock Out	☐ Off ☐ Every__hours ☐ Warn ☐ Lock Out	☐ Off ☐ Every__hours ☐ Warn ☐ Lock Out
Internal Simulator Schedule	Time interval when the internal Electronic Simulator test will be run. The behavior of the analyzer if the simulator test fails can also be specified. If the Schedule Option Lockout is selected, the analyzer will continue to perform the simulator test and will continue to display "FAIL" on subsequent cartridges until the test passes. If Lockout is not selected, the simulator test will not be initiated again until next scheduled time.	Off Interval of specified hours (1 to 65535 hours), and 8/24 (every 8 hours for blood gases and hematocrit and every 24 hours for other tests.)	Off Interval of specified hours (1 to 65535 hours), and 8/24 (every 8 hours for blood gases and hematocrit and every 24 hours for other tests.)	Interval 24 hours. Lockout	☐ Off ☐ Every__hour ☐ Warn ☐ Lock Out ☐ 8/24 ☐ Warn ☐ Lock Out	☐ Off ☐ Every__hour ☐ Warn ☐ Lock Out ☐ 8/24 ☐ Warn ☐ Lock Out	☐ Off ☐ Every__hour ☐ Warn ☐ Lock Out ☐ 8/24 ☐ Warn ☐ Lock Out	☐ Off ☐ Every__hour ☐ Warn ☐ Lock Out ☐ 8/24 ☐ Warn ☐ Lock Out
Strip Control Schedule	Schedule for control options.	Off, Every ___ hours (1 to 65535 hours), Every ___ Patient Tests (0 to 255 tests), and up to three predetermined times daily. The behavior of analyzer if the schedule is not met can also be specified. Options are: Warn (start-up warning) or Lockout (disable test strip testing until QC run).	N/A	Off	☐ Off ☐ Every__hour ☐ Every__ patient tests ☐ Time of Day 1_____ 2_____ 3_____ ☐ Warn ☐ Lock Out			
Strip Control Test Settings	Prompt or no prompt for Normal/(mid) Level Control. Comment code when a value is in-range. Comment code when value is out of range.	Disabled (no prompt for comment code), Allow no Comment (comment code optional), Require Comment. Disabled (no prompt for comment code), Allow no Comment (comment code optional), Require Comment. A comment code of 3 characters is allowed.	N/A	No prompt for Normal /(mid) Level Control and no prompt for Comment Code	☐ Prompt for Normal Level ☐ Comment Code in Range Results ☐ Optional ☐ Required ☐ Comment Code out of Range Results ☐ Optional ☐ Required	☐ Prompt for Normal Level ☐ Comment Code in Range Results ☐ Optional ☐ Required ☐ Comment Code out of Range Results ☐ Optional ☐ Required	☐ Prompt for Normal Level ☐ Comment Code in Range Results ☐ Optional ☐ Required ☐ Comment Code out of Range Results ☐ Optional ☐ Required	☐ Prompt for Normal Level ☐ Comment Code in Range Results ☐ Optional ☐ Required ☐ Comment Code out of Range Results ☐ Optional ☐ Required

Results Reporting Options

Option	Description	Choices i-STAT1	Choices Port. Clin. An. & BAM	Default0	New Default	Loc:_______	Loc:_______	Loc:_______
Analyte Enabled	Tests can be disabled. If disabled, the test will not appear in the Operator Test Selection list or on the results page and test results will not be stored.	Each test can be disabled.	Each test can be disabled.	All tests enabled	Disable: ____ ____ ____ ____	Disable: ____ ____ ____ ____	Disable: ____ ____ ____ ____	Disable: ____ ____ ____ ____
Reference Ranges	Reference ranges can be defined for each test. The ranges will be depicted as tic marks on the bar graphs on the result pages. There are no bar graphs for blood gases and ACT.	Ranges can be edited for each test.	N/A	Ranges are listed in the Cartridge and Test Information sheets and the Precision PCx Glucose Test Strip package inserts.	See Reference Range Worksheet.			
Action Ranges	High and low action ranges can be defined for each test.The action ranges for glucose apply to both the cartridge and the test strip.	Enter ranges.	N/A	Disabled	See Action Range Worksheet.			
Operator Test Selection	Requires the operator to select tests to be reported from a cartridge test panel.	Disabled Enabled	Disabled Enabled	Disabled				
Hematocrit Options	Reference anticoagulant used to calculate hematocrit result. CPB options.	K3EDTA or K2EDTA/Heparin/None. (NaEDTA is included in this option and None means no anticoagulant.) Prompt or no prompt for CPB compensation when cartridge includes hematocrit sensor, and if no prompt, automatically Adjust or Do not adjust.	Report CPB always ☐ On ☐ Off	K3EDTA Prompt CPB	☐ K3EDTA ☐ K3EDTA ☐ Prompt CPB ☐ Adjust ☐ Do not adjust			
Decimal Separator		Select comma (,) or period (.)	Select comma (,) or period (.)	Period				
Base Excess Calculation		Select Base Excess of Extracellular Fluid (BEecf) or Base Excess of Blood (BEb).	Select Base Excess of Extracellular Fluid (BEecf) or Base Excess of Blood (BEb).	BEecf				

Test Strip Lots

Option	Description	Choices i-STAT1	Choices Port. Clin. An. & BAM	Default0	New Default	Loc:________	Loc:________	Loc:________
Test Strip Lot Numbers	Up to 5 test strip lot numbers of 14 characters each can be entered. Upper and lower ranges for low, mid, and high controls for each test strip lot can be entered.	Lot numbers and control ranges can be entered.	N/A	Blank				
Test Strip Lot Not on List Action	Behavior of analyzer when a scanned/entered test strip lot is not on the test strip lot list.	Allow test to continue without warning, Warn (and prompt to continue), Lockout (disable testing until valid test strip lot number is scanned/entered).	N/A	Disabled	☐ Disabled ☐ Warn ☐ Lock Out			

ANALYZER CODED MESSAGES

From the time it powers up until the time it powers down, the i-STAT® Analyzer performs numerous quality checks. The failure of any quality check causes the analyzer to halt the test cycle and display a "cause" and an "action" message and a code.

The Cause Message:	This message describes the likely cause of the failed quality check. For example, when an overfilled cartridge is detected, the analyzer will display "Sample Positioned Beyond Fill Mark".
The Action Message:	This message indicates the appropriate action. For example, if it is likely the quality check will fail again the next time the analyzer is used, the instruction "Use Electronic Simulator" will be displayed. If the problem is related to an operator or cartridge, the instruction "Use Another Cartridge" will be displayed.
The Cause Code:	This is a numeric code associated with the failed quality check. Since multiple codes can be associated with a single cause message, this is essential information when contacting i-STAT Technical Support or your local support organization for further assistance. The codes are stored in the analyzer's memory along with other test records and are transmitted to the Central Data Station. The code list can be viewed and printed.

Codes 1-14 usually indicate a condition related to the environment or the state of the analyzer. These conditions are usually benign and go away after the next cartridge or an Electronic Simulator is inserted, or after the offending condition is corrected.

Code Number	Cause/*Action* Message on Display	Explanation
1	**Dead Batteries** / *Replace Batteries*	Replace disposable batteries or recharge rechargeable battery.
2	**Temperature Out of Range** / *Check Status Page*	The analyzer is recording a temperature outside its operating range. Move the analyzer to an area within the operating temperature of the test being performed and allow the analyzer to come to the new room temperature. Check the analyzer's temperature reading on the analyzer's Status Page.
3	**New Software Installed** / *Use Electronic Simulator*	This message appears on the Portable Clinical Analyzer after new software has been installed or, in some cases, when a new customization profile is received.

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Code Number	Cause/*Action* Message on Display	Explanation
4, 8	**Analyzer Interrupted** / *Use Another Cartridge*	The analyzer has detected that the last test cycle was not completed. This can happen if the batteries were removed or were making poor contact while a cartridge was still in the analyzer. Batteries that are too short will not make good contact. Check that batteries are inserted properly and seated well in the analyzer; check the battery voltage on the analyzer's Status Page and replace batteries if low. NOTE: Patient results displayed before this code are valid.
5, 6, 9	**Analyzer Interrupted** / *Ready for Use*	The Portable Clinical Analyzer is unable to refresh the display. This can happen if power is interrupted before the analyzer powers itself down. Check that batteries are inserted properly and seated well in analyzer. Batteries that are too short will not make good contact. Check battery voltage on Status Page.
7	**Batteries Changed** / *Ready for Use*	This is a normal response on the Portable Clinical Analyzer when the batteries are changed after a code 1 has occurred.
10	**Temperature in Range** / *Ready for Use*	Temperature is back in range after a code 2 on the Portable Clinical Analyzer.
11	**Date Invalid** / *Check Clock*	If the date in the real time clock precedes the release date programmed into the application software, code 11 is triggered. Check the date of the real time clock. The accuracy of the clock is checked at the beginning of a coagulation test. If the clock is inaccurate, Code 11 is triggered.
12	**Invalid or Expired CLEW** / *See Manual*	The CLEW standardization set has expired. Download a valid CLEW. Date of the real time clock exceeds the expiration date of the CLEW software. Check the date of the real time clock.
13	**Invalid or Expired CLEW** / *See Manual*	The CLEW is corrupt or not compatible with the application software (JAMS) or there is no CLEW in the anlyzer. Download a valid CLEW. If this code occurs after a software upgrade and customization is enabled, change the CLEW version in the Customization Profile to the latest version and re-transmit the profile to the analyzer.
14	**Analyzer Error** / *See Manual*	Customization profile is corrupted. Retransmit the customization profile. If code 14 reoccurs, contact i-STAT Technical Support or your local support organization for further assistance.
95	**Test Cancelled by Operator**	This message will appear in the stored test records on the i-STAT1 Analyzer if the analyzer powers down before mandatory information was entered.

The following codes are associated with the cartridge or fluid movement within a cartridge. These conditions can be operator or sample related. In most cases, a new cartridge must be used. If a condition persists, especially if isolated to one analyzer, there may be an analyzer problem.

Code Number	Cause/*Action* Message on Display	Explanation
22	**Cartridge Error** / *Use Another Cartridge*	This code occurs only for coagulation cartridges if the mixing of sample and reagent is compromised. This can be caused by insufficient or clotted sample.

Code Number	Cause/*Action* Message on Display	Explanation
24	**Cartridge Error** / *Use Another Cartridge*	Electrical resistance of the calibrant fluid used to verify the electrolyte concentration is out of specification. This could occur if the calibrant pack was ruptured well before the test allowing evaporation to result in a higher electrolyte concentration. Besides the electrolyte concentration, the electrical resistance of the calibrant fluid is also affected by the temperature and the height and width of the fluid segment over the conductometric sensor. The analyzer accounts for the temperature, but the height and width of the fluid segment can vary from cartridge lot to cartridge lot. The analyzer has been programmed to compensate for height and width differences typical for each lot by maintaining a running average of the resistances measured from the most recent cartridges. Occasionally the differences between two lots is large enough to cause the introduction of a new lot to trigger code 24 on the first few cartridges used. Code 24 will disappear as the running average adjusts. If code 24 persists after more than 3 cartridges on each analyzer, contact i-STAT Technical Support or your local support organization for further assistance.
26	**Cartridge Error** / *Use Another Cartridge*	This code occurs if there was a coagulation specific quality check failure: premature substrate activation, abnormally low levels of substrate, or invalid fluid motion.
20,27–29, 32, 33, 41, 87	**Cartridge Error** / *Use Another Cartridge*	These codes identify problems with the cartridge such as calibrant fluid arrival too soon or too late or not at all, or noise in calibrant fluid signals. Codes 20, 27, and 41 can be caused by poor contact which can sometimes be corrected by a pin conditioning procedure described at the end of this bulletin.
42,43	**Cartridge Error** / *Use Another Cartridge*	These codes indicate that the conductometric sensor (code 42) or amperometric sensor (code 43) was out of specification. This could be caused by a pre-burst calibrant pack, dirty cartridge contact pads or a dirty connector in the analyzer.
79–81	**Cartridge Error** / *Use Another Cartridge*	Bad contact between the thermal probes and the metalization on the back of the chips in the cartridge trigger these codes. Causes are poor metalization of chips, dirt on the metalization, or bent or broken thermal probes in the analyzers.
21	**Cartridge Preburst** / *Use Another Cartridge*	This code indicates that the analyzer detected fluid on the sensors before it should have. Possible causes: poor storage conditions of cartridges (frozen), or mishandling of cartridges (putting pressure in the center of the cartridge), or rerunning used cartridges. Try another cartridge.

Code Number	Cause/*Action* Message on Display	Explanation
31, 34, 44	**Unable to Position Sample** / *Use Another Cartridge*	The analyzer did not detect movement of sample across the sensors. This could be due to not closing the snap closure on the cartridge, to a clot in the sample preventing movement of the sample, or to an aberrant cartridge.
35, 36	**Sample Positioned Short of Fill Mark** / *Use Another Cartridge*	The cartridge was underfilled or the sample has clotted. The sample must reach the fill mark. Try another cartridge.
30, 37	**Sample Positioned Beyond Fill Mark** / *Use Another Cartridge*	The cartridge was overfilled. The sample was past the fill mark. Try another cartridge.
38	**Insufficient Sample** / *Use Another Cartridge*	This is most likely due to insufficient sample in the sample well of the cartridge, but will also be caused by bubbles in the sample. Try another cartridge and ensure sufficient sample is in the sample well.
47	**Cartridge Not Inserted Properly** / *Reinsert Cartridge*	The code indicates the cartridge or Electronic Simulator may not be pushed in all the way. Reinsert the cartridge or Electronic Simulator. If problem is recurrent and/or the user is certain the cartridge or Simulator is properly inserted, it may indicate an instrument problem. Contact i-STAT Technical Support or your local support organization for further assistance.
48	**Analyzer Error** / *See Manual*	This code indicates the cartridge or Electronic Simulator may have been "cocked" when inserted. Push cartridge or Simulator straight through the cartridge port. If problem is recurrent and or the user is certain the cartridge or Simulator is properly inserted, it may indicate an analyzer problem. Contact i-STAT Technical Support or your local support organization for further assistance.

The following conditions are related to electronic or mechanical failures in the analyzer.

Code Number	Cause/*Action* Message on Display	Explanation
50, 51	**Analyzer Error** / *Use Electronic Simulator*	Running a simulator may not detect these problems. Run the simulator and if the analyzer passes, run a cartridge to see if the code reoccurs. If not, continue to use the analyzer. If the code reoccurs, contact i-STAT Technical Support or your local support organization for further assistance.
52	**Analyzer Error** / *Use Electronic Simulator*	Run a simulator. If the error occurred while running an ACT cartridge, also run a cartridge. If the code does not reoccur, continue to use the analyzer.
58–62	**Analyzer Error** / *Use Electronic Simulator*	The analyzer usually recovers from these error conditions. These error conditions can be detected by the Electronic Simulator. If the analyzer passes the Electronic Simulator test continue to use it. If not, check the battery voltage and check the analzyer with another simulator to rule out a simulator problem. If the code persists, contact i-STAT Technical Support or your local support organization for further assistance.

Code Number	Cause/*Action* Message on Display	Explanation
23, 53, 63, 65–68, 70, 72–74, 82, 85, 86, 89–94, 96, 97	**Analyzer Error** / *See Manual*	These are mechanical or electronic failures from which the analyzer may not be able to recover. Code 70 can occur on the Portable Clinical Analyzer if the user presses the DIS key before the Electronic Simulator is run after a software update. If this happens, reseat the batteries to reset the analyzer and run the Electronic Simulator. For other codes, use the Electronic Simulator twice, then use a cartridge with a sample. If the analyzer passes the simulator check and a quality check code does not occur with the sample, continue to use the analyzer. If code 23 occurs, try the pin conditioning procedure. If the analyzer does not pass the simulator check and/or a quality check code occurs with the sample, contact i-STAT Technical Support or your local support organization for further assistance.
69	**Cartridge Type Not Recognized** / *Use Another Cartridge*	This code could be due to use of a cartridge type which is not compatible with the version of software in the analyzer. If this is a new cartridge type, contact i-STAT Technical Support or your local support organization for a software update. If the cartridge type has been used successfully before, the condition may be due to an aberrant cartridge. If the condition occurs repeatedly on one analyzer, the analyzer may need repair. Code 69 could also be caused by an expired cartridge. Contact i-STAT Technical Support or your local support organization for further assistance.

Codes 100-107 indicate a condition with the PCx Glucose Test Strip on the i-STAT Analyzer.

Code Number	Cause/*Action* Message on Display	Explanation
100	**Strip Error** / *Use Another Strip*	The test strip or the test port is wet, defective, contaminated, or the wrong test strip was inserted. Remove the test strip. Press 1 for Test Options. Press 1 for Same Patient or Level. Repeat the test.
101	**Strip Error** / *Use Another Strip*	The test strip was removed from the test port during testing. Press 1 for Test Options. Press 1 for Same Patient or Level. Repeat the test.
103, 105, 106, 107	**Strip Error** / *Use Another Strip*	Test unsuccessful. An error was detected during the analysis sequence. Remove the test strip. Press 1 for Test Options. Press 1 for Same Patient or Level. Repeat the test. If the problem persists, record the three digit error code and contact MediSense support services or your local support organization.
102, 104	**Strip Error** / *Use Another Strip*	The test strip malfunctioned or the blood glucose level is beyond the measuring capability of the test strip and strip reader. Remove the used test strip. Press 1 for Test Options. Press 1 for Same Patient or Level. Repeat the test with a new test strip. If the error occurs again, confirm the result by performing the test by a different method. Contact MediSense support services or your local support organization.

Code Number	Cause/*Action* Message on Display	Explanation
108, 109	**Temperature Out of Range /** *Check Status Page*	During the test, room temperature became unstable or moved outside the limits within which the test strip reader can perform a test. Ensure that the room temperature is within the specified limits. Allow the analyzer to stabilize to room temperature: 15 to 40°C or 59 to 104°F. Press the Menu key until the Administration Menu is displayed. Press 1 for Analyzer Status where the room temperature reading is displayed.

The following conditions are related to the Electronic Simulator:

Code Number	Explanation	How to Respond
Numerical code	See under Quality Check Codes	See under Quality Check Codes
L	Potentiometric channel out of limits. Can occur if moisture collects on the contact pins inside the analyzer when analyzer is subjected to ambient temperature change.	Allow analyzer to equilibrate in new environment for 30 minutes and repeat test.
G	Amperometric channel out of limits. Can occur if external simulator not inserted straight.	Reinsert simulator straight. If code reoccurs, return analyzer.
R, r	Resistant reading on hematocrit channel out of limits.	Try pin conditioning procedure.
T, t	Thermal probe failure.	Return analyzer.
B	Potentiometric channel out of limits.	Return analyzer.

NOTE: Any time repetitive codes occur which cannot be addressed or corrected through training, contact i-STAT Technical Support or your local support organization for further assistance.

PIN CONDITIONING PROCEDURE

This procedure may correct the condition that triggered codes 20, 23, 27 and 41 and Electronic Simulator failures with codes R, r, L and G.

Step	Action
1.	Select a cartridge, new or used, with the most number of contact pads.
2.	Lightly scratch across the surface of the contact pads with the end of a paper clip.
3.	Insert the cartridge. Allow test cycle to finish. Ignore any quality check codes.
4.	Reinsert the same cartridge four more times.
5.	Insert an Electronic Simulator if correcting for codes R, r, L or G or a new cartridge with sample if correcting for a quality check code.
6.	If a code reoccurs, the analyzer must be returned. If not, continue to use the analyzer.

HEMATOCRIT DETERMINATION IN THE i-STAT® SYSTEM AND COMPARISON TO OTHER METHODS

This bulletin describes the three most common methods for determining hematocrit (microhematocrit, conductometric and, as calculated by automated cell counters) and the common interferences which lead to discrepancies among the three methods.

The i-STAT System uses the conductivity method to determine hematocrit. The Point-of-Care Testing Coordinator should ensure that end users are aware of factors affecting results obtained on the i-STAT System. Factors affecting hematocrit are included in this Technical Bulletin. For factors affecting other tests, refer to the Cartridge and Test Information sheets included in the i-STAT System Manual.

HEMATOCRIT

NCCLS recommends that the term hematocrit be used to describe the materials and/or method used to measure Packed Cell Volume (PCV). PCV is defined as the measure of the ratio of the volume occupied by the red cells to the volume of whole blood in a sample of capillary or venous blood. This ratio is measured after appropriate centrifugation and should be expressed as a decimal fraction.[1,2]

i-STAT Corporation has retained the term hematocrit for the measured quantity and, according to common practice, expresses hematocrit as a percentage, in units of Percent Packed Cell Volume (%PCV). A hematocrit of 0.45 PCV is expressed as 45 %PCV.

THE METHODS

The Microhematocrit Method

Microhematocrit is the standard method for hematocrit determination[1,2.] An anticoagulated sample in a microcapillary tube is spun in a centrifuge. The red blood cells are separated from the plasma by the centrifugal force (at least ten thousand times the force of gravity). The height of the separated red blood cell column is compared to the height of the entire column to determine the packed cell fraction (i.e. the hematocrit).

The hematocrit of a sample can be altered by the anticoagulant. The most popular anticoagulant used for hematocrit determinations on automated hematology analyzers in the United States is K_3EDTA. It is well documented that K_3EDTA causes the cells to shrink by increasing the osmotic pressure in the plasma[1,2,3,4,5], thus reducing the hematocrit below its value *in-vivo*. Current literature indicate that the hematocrit is reduced between 1.5 %PCV and 2.2 %PCV at normal hematocrit levels. Experiments conducted by i-STAT Corporation indicate a shrinkage of about 2 %PCV at normal hematocrit levels.

Both the past NCCLS (H7-A) recommendation for microhematocrit determination, and the current (H7-A2) recommendation, call for the use of anticoagulants which do not affect the cell sizes (Na_2EDTA and K_2EDTA respectively[1,2]). Both documents carry specific recommendations against K_3EDTA. Nevertheless K_3EDTA remains the most popular anticoagulant in health care institutions in the United States because it is a liquid in commercially available collection tubes and thus easier to use. As a result, automated hematology analyzers are calibrated to match microhematocrit determinations on samples anticoagulated with K_3EDTA.

The Conductivity Method

Systems using the conductivity method, such as the i-STAT System, measure the electrical conductance of a whole blood sample. Plasma conducts electrical current, blood cells act as insulators. A sample with a relatively high hematocrit has, by definition, a larger proportion of its volume filled by the non-conductive red blood cells. The overall conductance of the sample will thus be relatively low. In the i-STAT System, before the measured sample conductance is converted into a hematocrit value, corrections are applied for the temperature of the sample, the size of the fluid segment being measured, and the relative conductivity of the plasma component. The first two corrections are determined from the measured value of the calibrant conductance and the last correction from the measured concentrations of sodium and potassium in the sample.

The i-STAT System was originally calibrated to match microhematocrit determinations on samples anticoagulated with lithium heparin which does not shrink the cells. However, most hospital laboratories use automated hematology analyzers as the primary systems for hematocrit determinations and, as discussed, it is common practice for these analyzers to be calibrated to match the microhematocrit method for samples anticoagulated with K_3EDTA. To minimize confusion at the majority of institutions where the i-STAT System will be used, the system is now calibrated to match microhematocrit determinations on samples anticoagulated with K_3EDTA.

This decision had to be carefully considered because the hematocrit determination delivered by the i-STAT System is now less reflective of the hematocrit *in-vivo*. Nonetheless, i-STAT Corporation feels the advantages of minimizing confusion outweighs the significance of reporting results biased versus the true value. Should the community move towards calibrating against samples anticoagulated with K_2EDTA as per the NCCLS recommendation, i-STAT will reestablish its calibration values.

Automated Hematology Analyzer Methods

Automated hematology analyzers do not directly measure hematocrit. They calculate hematocrit from measurements of individual cell sizes and counts. The sample is diluted with an isotonic buffered aqueous solution and passed through a measuring orifice. Individual cells are counted and sized by one of two basic mechanisms. Either fluctuations in electrical conductivity, or the scatter of collimated light, is measured as cells pass through the orifice. The hematocrit of the original sample is calculated from the number of cells, the sizes of the cells and the volume of diluted solution passing through the orifice.

METHOD COMPARISONS

The discrepancy between the hematocrit values determined by two different systems on an individual sample has three components: a random component, a systematic component and a method dependent/sample specific component.

Random Component

The random component results from the combination of each system's imprecision. The size of the component is different on each determination. (The imprecision of the i-STAT System is typically about 0.6 to 0.7 %PCV.)

Systematic Component

The systematic component results from differences in the systems' calibration and is constant from sample to sample.

Method Dependent/Sample Specific Component

The method dependent/sample specific component results from the specific interferences which affect different measurement methods. Each sample has specific characteristics which may cause different methods to have different types and sizes of measurement error.

The method dependent/sample specific component is commonly observed as a random difference between dissimilar methods. It can, however, also cause an apparent systematic difference component when a particular sample population has a systematic characteristic. For example, a population of samples with low mean cell hemoglobin concentration (MCHC) will cause a systematic negative bias on determinations by some automated hematology analyzers when compared to determinations from both microhematocrits and conductivity systems.

LIMITATIONS OF THE METHODS

Microhematocrit

Excess anticoagulant will shrink the cells and decrease the hematocrit value. Older literature suggests that cells with abnormal morphology, such as found in sickle cell anemia, spherocytosis and thalassemias, cause an increase in trapped plasma and therefore an increase in the PCV. Later literature suggests this may not be the case (see Mean Cell Hemoglobin Concentration under Automated Hematology Methods).

Conductivity Methods

Electrolyte Concentration

The conductivity of the whole blood sample is dependent upon the concentration of electrolytes in the plasma portion. The i-STAT System corrects for the concentration of electrolytes using the measured value of sodium and potassium. The interference is minimized to an insignificant level.

Other Non-Conducting Elements[34,35,36,37,38,39]

The conductivity method does not distinguish red blood cells from other non-conducting elements such as proteins, lipids and white blood cells which occupy volume in the sample. The i-STAT System is calibrated to read hematocrit accurately when these other elements are at normal levels.

Total Protein

At hematocrit levels less than 40 %PCV, the reading will increase by approximately 1 %PCV for each g/dL the protein level is increased outside the normal range of 6.5 to 8.0 g/dL. At hematocrit levels less than 40 %PCV, the reading will decrease by approximately 1 %PCV for each g/dL the protein level is decreased outside the normal range of 6.5 to 8.0 g/dL. At hematocrit levels greater than 40 %PCV the interference is about three quarters that size.[40]

It is important to be aware of the total protein level when using conductivity systems to monitor a patient on a cardiopulmonary bypass pump (see reference 39). If albumin, or other colloid, is not added to the pump's priming solution, the plasma protein will drop by about 3 to 4 g/dL. The conductivity reading will then be systematically low by 3 to 4 %PCV.

It is also important to be aware that the total protein level in premature neonates can be in the range of 3.6 to 6.0 g/dL.[41]

Lipids

Interference from lipids will be about two-thirds the size of the interference from proteins. The protein interference is larger because it is a charged non-conducting element.

WBC

Interference from white blood cells depends upon the size of the cell. As an example the hematocrit reading will be increased by one unit when the white cell count is 50,000 per microliter if we assume the average white blood cell occupies twice the volume of an average red blood cell.

Automated Hematology Methods

Osmolality:[17,18,19,20,21,22,23,24,25,26,27,28]

Abnormal sample osmolality can create discrepant readings as the red cells shrink or swell to achieve osmotic balance with the isotonic (normal osmolality) diluent. Differences up to 10 %PCV have been reported for glucose concentrations in the range of 1000 to 2000 mg/dL. Differences up to 5 %PCV have been reported for samples with low or high sodium concentrations.

Cold Agglutinins:[29,30,31,32,33]

Under the right conditions of diluent temperature, red blood cells from certain samples will clump together. The large clumps will not be recognized as red blood cells by certain automated hematology analyzers, and thus the overall red blood cell count and the calculated hematocrit, will be falsely low. In extreme cases, the hematocrit can read low by up to about 8 %PCV.

Mean Cell Hemoglobin Concentration:[12,13,14,15,16]

Red blood cells can deform under the pressure experienced when being sent through the measuring orifice. This is particularly true for electrical impedance methods. Cells with lower hemoglobin concentrations will deform to a greater degree. This can create errors as large as 3 %PCV.

Early authors attributed the discrepancy between automated hematology determinations and reference microhematocrit determinations to variabilities in trapped plasma on the microhematocrit determination.[6,7,8,9,10,11] It is only recent authors that have recognized the substance of the discrepancy to be an interference on the automated method.

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TECHNICAL
BULLETIN

Proficiency Testing on the i-STAT® System

Proficiency Testing

CLIA regulation *Subpart H – Participation in Proficiency Testing* requires a laboratory to enroll in a proficiency testing program approved by the Health Care Financing Administration (HCFA) for its primary test system or that system used at its primary site. The laboratory must participate successfully as defined by the criteria defined in *Subpart I – Proficiency Testing Programs.*

A primary testing system is defined as the only method or the primary method for performing and reporting tests under a CLIA certificate. The i-STAT System is a primary testing system when:

- A hospital has separate CLIA certificates for the main laboratory and point of care testing;
- A hospital owns a clinic, same-day surgery, kidney dialysis unit, etc., which requires a separate CLIA certificate;
- The i-STAT System is the hospital's primary laboratory testing system; or
- The i-STAT System is the main testing system in a physician's office, skilled nursing facility, unaffiliated patient transport service, home healthcare agency, etc.

Proficiency testing (PT) programs must provide three separate shipments during the year that include five challenges for each analyte or test. Laboratories must test samples as they would patient samples and return the results within a specified time to the provider for grading.

The i-STAT System

The i-STAT System consists of any number of i-STAT Portable Clinical Analyzers, i-STAT 1 Analyzers and Phillips Medical Systems Blood Analysis Modules (collectively known as "Analyzer"). All Analyzers that pass the Electronic Simulator test are equivalent. Therefore, PT samples can be tested on any Analyzer that has passed the Electronic Simulator test.

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PT programs for the i-STAT System

There are several national HCFA approved PT program providers such as the College of American Pathologists (CAP), the American Association of Bioanalysts (AAB), and the American Proficiency Institute (API). Several states have HCFA approved PT programs as well. Each of these providers has several PT surveys to choose from. In general, aqueous-based PT surveys are recommended. Certain PT survey samples are not compatible with the sensors and may contain interfering substances that could affect results.

- Fluorocarbon samples for blood gases and fixed-cell samples for hematocrit are not compatible with the sensors.

The CAP's AQ2 survey provides both aqueous and protein based samples and is the most comprehensive of the PT surveys including all analytes available on the i-STAT System with the exception of ACT (Activated Clotting Time). The AAB's Activated Clotting Time survey is the recommended Coagulation survey.

Thermally controlled cartridges (cartridges with 37°C symbol on the pouch) may give different results from non-thermally controlled cartridges **WHEN USING AN AQUEOUS SAMPLE**. Therefore, it is important to code correctly for thermally controlled and non-thermally controlled samples when reporting PT results (see below). All cartridge types have equivalent results when using a whole blood sample.

The i-STAT System allows users the option to choose special standardization settings and alternate versions of operating software. Specifically for hematocrit analysis, it is recommended that users measure proficiency testing samples on analyzers that are customized for K3EDTA rather than K2EDTA and **Do Not** apply CPB sample type. For blood gas parameters, it is recommended that users measure proficiency testing samples on analyzers that are configured with the standard version of JAMS software.

CAP Surveys Program

Instrument Codes The proper code is determined not by the i-STAT Analyzer but rather by the specific i-STAT Cartridge used to analyze the sample.

Cartridge Type

37° cartridges
G3+, EG6+, EG7+, CG8+, CG4+, and CREA

Non 37° cartridges
G, E3+, EC4+, 6+, EC6+ and EC8+

Instrument Codes

i-STAT 37° cartridges	**1262**
i-STAT Non 37° cartridges	**1039**

College of American Pathologists
325 Waukegan Road
Northfield, IL 60093-2750
800-323-4040 or 847-832-7000

AAB Proficiency Testing Service

Method Code for ACT (Activated Clotting Time): **600**

American Association of Bioanalysts (AAB)
AAB Proficiency Testing Service
205 West Levee St.
Brownsville, Texas 78520
800-234-5315

API Proficiency Testing Program

i-STAT Proficiency Testing Program

Indicate thermal or non-thermal for each analyte.

thermal (37°) cartridges
G3+, EG6+, EG7+, CG8+, CG4+, and CREA

non thermal (non 37°) cartridges
G, E3+, EC4+, 6+, EC6+ and EC8+

American Proficiency Institute
1159 Business Park Drive
Traverse City, MI 49686
800-333-0958

WSLH - Wisconsin State Laboratory of Hygiene

Method Code for Activated Clotting Time (CT) **3671**

Method Code for thermal (37°) cartridges **3671**
G3+, EG6+, EG7+, CG8+, CG4+, and CREA

Method Code for non-thermal (non 37°) cartridges **3670**
G, E3+, EC4+, 6+, EC6+ and EC8+

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i-STAT

TECHNICAL BULLETIN

COMPENSATION FOR EXTREME ALTITUDE AND BAROMETRIC PRESSURE ON PO2 RESULTS IN AQUEOUS MATERIALS

What is barometric pressure?

Barometric pressure is a measure of atmospheric pressure and is influenced by changes in altitude and weather conditions. The atmospheric pressure is approximately 760 mmHg at sea level. Oxygen constitutes approximately 20.9% of this pressure or 159 mmHg at sea level.

Oxygen pressure and aqueous solutions

The partial pressure of oxygen in a solution will change as it attempts to equilibrate to the surrounding ambient pressure. The rate of change is faster in aqueous material than in whole blood samples due to the absence of red blood cells containing hemoglobin which bind oxygen molecules. This is of practical significance when testing aqueous materials on blood gas analyzers as there will be a detectable shift in the partial pressure of oxygen in the sample as it attempts to equilibrate to the flowpath.

Compensation factors for the i-STAT System

The ranges for i-STAT aqueous materials are established for the degree of equilibration which occurs in the i-STAT cartridge at or near sea level. The results for aqueous materials such as the i-STAT Calibration Verification Set, i-STAT Controls, and aqueous proficiency materials can be easily corrected for higher altitude environments. The formulas below should be applied to the observed PO2 results prior to comparing them to the published acceptable range for the level of material:

FOR PO2 VALUES BELOW 150 mmHg - Controls: Levels 1, 2, 3
Calibration Verification: Levels 4, 5

$$\text{PO2Corrected} = \text{PO2Observed} + (0.067 \text{ x } (760 - \text{BP}^*))$$

Approximate change: For every decrease of 15 mmHg in pressure (from 760 mmHg), add 1 mmHg to reading.

FOR PO2 VALUES ABOVE 150 mmHg - Calibration Verification: Levels 1, 2, 3

$$\text{PO2Corrected} = \text{PO2Observed} + (0.029 \text{ x } (760 - \text{BP}^*))$$

Approximate change: For every decrease of 35 mmHg in pressure (from 760 mmHg), add 1 mmHg to reading.

* Barometric pressure from analyzer displayed on status page.

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P/N: 014263-00 01A Art: 714263-00 A Rev. Date: 04/16/01

i-STAT

TECHNICAL BULLETIN

Hematocrit Determinations Using the i-STAT® System During Cardiopulmonary Bypass Procedures

Overview:

A new feature in the i-STAT System facilitates hematocrit determinations during cardiopulmonary bypass ("CPB") procedures. The feature automates a previously manual procedure for adjusting the result to compensate for the effects of low plasma protein concentrations typical of blood during bypass.

The adjustment can be automated even though protein is not directly measured by the system. The reason is that the protein concentration can be robustly inferred from the measured hematocrit in this clinical application. Inferential algorithms of this type have been incorporated into conductivity analyzers designed specifically for the CPB application.(1)

The new feature allows the user to configure the i-STAT System to act as a CPB specific analyzer for a particular cartridge by specifying the sample type as "CPB". The CPB algorithm is ***not*** employed unless the sample type is specified as "CPB". The i-STAT System thus defaults to acting as a general purpose device. This is important since a CPB specific algorithm can deliver results with medically significant error in other applications.

The feature is currently available only on i-STAT analyzers with thermal control capability. Although activating the feature is straightforward (see "Instructions for Use" below), it is important to understand the behavior of the algorithm for proper clinical application.

Background/Purpose

The i-STAT System employs the conductivity method for determining hematocrit(2), the defacto standard method employed by whole-blood combination analyzers. The effectiveness of this method is well established.

It is understood that the conductivity method essentially assays the sum of all non-conducting elements within the whole blood matrix: protein, white blood cells and lipids, as well as red blood cells. Thus variations from normal levels of these other constituents will directly interfere with the measurement of the volume of red blood cells. The most important interference is from variations in plasma protein concentrations.

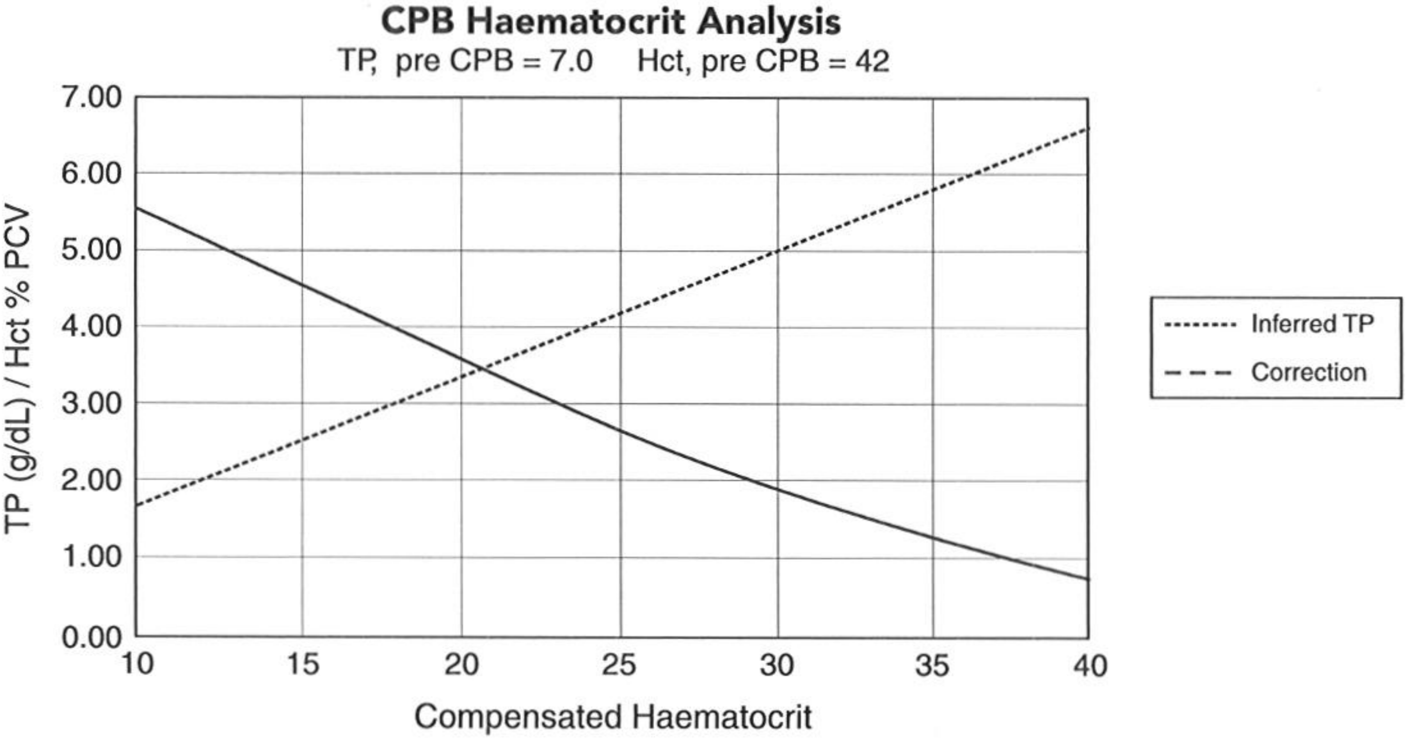
The magnitude of interference caused by changes in protein is no larger than that from interferences typical of other well accepted methods for determining hematocrit(3) (e.g. sodium, glucose and BUN interferes with electronic particle counters such as those distributed by Coulter Corporation or Sysmex Corporation.) However when used during CPB this particular interference is systematic. All samples have reduced protein, so all samples are affected.

Since the interference is systematic it can be easily compensated. Since initial introduction of the product, i-STAT has provided a compensation chart indicating the magnitude of this interference for given levels of protein. The effectiveness of the chart has been proven at multiple hospitals.

In practice, many users do not determine the protein level before using the chart. They have learned that the interference is generally 3 to 4 %PCV during bypass.(4)

The purpose of the new feature is to automate the compensation process. When "CPB" is chosen as the sample type, the algorithm infers the total protein level from the measured hematocrit and adjusts it as indicated by the compensation chart.

The algorithm infers the total protein level by assuming the pump priming solution dilutes the hematocrit and total protein equally. Modeling the pre-pump hematocrit as 42 %PCV and the pre-pump total protein as 7 g/dL, the following graph indicates the inferred total protein and resultant correction.



e.g. : uncompensated HCT = 21% PCV

21% PCV = .50 or 50%
42% PCV

inferred TP= 7.0g/dL x .50 = 3.5g/dL

21% PCV+ 3 = 24% PCV

Limitations

The algorithm is based upon a series of inferences:

- The algorithm models initial pre-CPB values for total protein and hematocrit (7 g/dL and 42 %PCV respectively). Although actual initial total protein and hematocrit values may be different than these, typical deviations rarely affect the accuracy of the correction by more than 0.5% PCV. More often than not the actual initial values are consistent with a "pre-dilution" of the modeled initial values.
- The algorithm assumes that the pump priming solution has no added albumin or other colloid. The algorithm will tend to overcorrect if solutions with added colloids are utilized, though the size of the overcorrection will seldom be more than 1 %PCV.
- Other therapies which effect the ratio of total colloids to hematocrit (administration of colloids, packed cells, etc.) will affect the inference.

It is therefore recommended that each practice verify the hematocrit determination for cardiopulmonary bypass procedures so that the impact of these limitations upon a particular practice's protocols is understood.

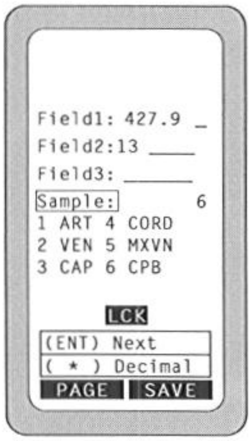
Instructions For Use

To obtain a "CPB" hematocrit result follow the directions below. These steps must be performed each time a cartridge is run and a "CPB" hematocrit is required. If you have any questions after you review this material, please do not hesitate to contact i-STAT Technical Service.

Step 1 - Once the cartridge is inserted into the Analyzer, enter both the patient and operator identification numbers.

Step 2 - While the Analyzer is running through the test cycle, press the PAGE key to obtain access to the data screen that permits the operator to input additional patient parameters.

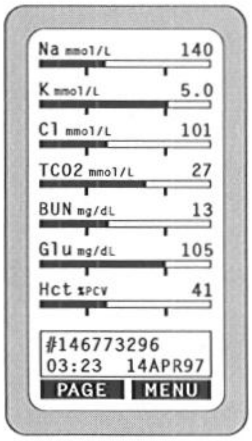
Step 3 - In order to obtain a CPB hematocrit result the operator must select "6 CPB" for "Sample:". After all information is entered, press the SAVE key. (See Figure 1)



```
Field1: 427.9 _
Field2:13 ____
Field3: ______
Sample:        6
1 ART 4 CORD
2 VEN 5 MXVN
3 CAP 6 CPB

      LCK
(ENT) Next
( * ) Decimal
PAGE  SAVE
```

Figure 1



```
Na mmol/L      140
K mmol/L       5.0
Cl mmol/L      101
TCO2 mmol/L     27
BUN mg/dL       13
Glu mg/dL      105
Hct %PCV        41
#146773296
03:23  14APR97
PAGE  MENU
```

Figure 2

Step 4 - Verify that the patient parameters input into the Analyzer are correct. Press the YES key to permanently save the information. To return to the results page, press the PAGE key. When the test cycle is complete, the CPB hematocrit will be displayed as ,CPB". (See Figure 2) This indicates that the CPB compensation has been applied. The hemoglobin level is calculated from the hematocrit and will be displayed as "Hb,CPB".

Special Notes:

- If the "CPB" sample type is chosen after the test cycle is complete, the analyzer's display will be redrawn with the modified hematocrit test result, and will be displayed as "Hct,CPB" and "Hb,CPB". Any printouts completed after this step will reflect the use of the CPB algorithm. The sample type cannot be modified once any of the following circumstances have taken place:
  - results have been transmitted
  - a stored result is retrieved from the analyzer's memory
  - a new cartridge is inserted into the analyzer
  - the Electronic Simulator is inserted into the analyzer
- The CPB algorithm is not employed unless the sample type is specified as "CPB". The i-STAT System thus defaults to acting as a general purpose device. This is of particular importance because a CPB specific algorithm can deliver results with medically significant error in other applications.

The Central Data Station and the CPB Hematocrit

The i-STAT Central Data Station (CDS) has a separate field to display the sample type. The abbreviation "CPB" will be displayed here for clinical interpretation and to provide an audit trail. The sample type can also be passed on to the LIS/HIS with the i-STAT AME interface. Since the CDS uses a fixed template for labeling the results, the "Hct" and "Hb" labels remain unmodified.

Footnotes

1. Riley JB, Burgess BM, Smith CA, Crowley JC, Soronen SW: In vitro measurement of the accuracy of a new patient side blood gas, pH, hematocrit and electrolyte monitor. J Extra-Corpor Technol 19[3]:322-329, 1987. (Note: this study relates to the GEM line of analyzers currently distributed by Malinckrodt)

2. Hematocrit determination in the i-STAT System and comparison to other methods, i-STAT Technical Bulletin #012072-01.

3. (Note: see multiple references in Technical Bulletin referenced in 2. above)

4. Connelly NR, Magee M, Kiessling B: The relationship between i-STAT derived hematocrit and laboratory and centrifuged hematocrit values in patients undergoing cardiopulmonary bypass. Poster presentation at the American Society of Cardiovascular Anesthesiologists, May 1995, Philadelphia.

i-STAT

TECHNICAL BULLETIN

i-STAT INTERNAL ELECTRONIC SIMULATOR

The i-STAT internal Electronic Simulator is a tool which helps users of the i-STAT System ensure proper compliance to established QA regimens and requirements. Built into each i-STAT® Portable Clinical Analyzer with thermal control and each HP M1022A Blood Analysis Module for OmniCare CMS Patient Monitors (collectively referred to as "Analyzer") is an Electronic Simulator circuit. This circuit performs the same functions as the external Electronic Simulator. The internal Electronic Simulator allows users to eliminate the time required to locate and test each Analyzer with the external Electronic Simulator.

This bulletin covers issues related to the internal Electronic Simulator in a *Frequently Asked Question* format.

OPERATION

How does the Analyzer use the internal Electronic Simulator?

The Analyzer Customization Profile Utility (customization utility) is used to enable the internal Electronic Simulator. The customization utility is a part of the i-STAT Central Data Station. Without a Central Data Station, the internal Electronic Simulator cannot be enabled.

How often does the internal Electronic Simulator run?

Each facility can set the frequency using the customization utility. A set number of hours between tests or an 8/24 hour combination (8 hours for blood gas and hematocrit channels, 24 hours for all other channels) can be specified. This functionality is for compliance with current regulations in the US.

The internal Electronic Simulator test is triggered by inserting a cartridge. If the software detects that the specified time has elapsed since the last Electronic Simulator test (internal or external), it will automatically perform the internal test before the sample is tested. If the test fails, the sample is not analyzed.

Note that the actual elapsed time between internal Electronic Simulator tests can be greater than the specified time if the Analyzer is not used. This does not violate the established protocol since the next sample is tested only after the internal Electronic Simulator test has run on that cartridge and only if the test is successful.

How do I know the internal Electronic Simulator test is running?

The test is performed about ten seconds into the test cycle. On the handheld analyzer, the message "Electronic Simulator" is displayed on the screen just as when the external test is performed. On the Blood Analysis Results or Setup screen of the CMS, the message is "Internal Simulator test running". With all Analyzers, a failed Simulator test stops the testing cycle, and the "FAIL" Simulator result will be displayed on the screen. If the test passes, the cartridge cycle continues to completion and the cartridge results are presented to the user in the standard way.

How much time does the internal Electronic Simulator test add to the test cycle of a cartridge?

The internal Electronic Simulator test adds about 15 to 20 seconds to the cycle. The Simulator test result is available about thirty seconds from the beginning of the cycle as the test begins about ten seconds into the cycle.

How are the results of an internal Electronic Simulator test recorded by the i-STAT System?

The electronic documentation when using the internal Electronic Simulator is essentially the same as when using the external Electronic Simulator. The results of the Simulator test are stored as a distinct record and can be downloaded to the Central Data Station.

2ec

There is a small difference in documentation in the Central Data Station. Electronic Simulator records resulting from an external test will display the temperature of the external Electronic Simulator in the "Patient Temperature" field. This field will be blank in Electronic Simulator records resulting from an internal test.

Why is the internal Electronic Simulator sometimes activated multiple times within the specified period?
The internal Electronic Simulator will test only those measurement channels that it detects will be used with the cartridge which activates the cycle. As an example, if a G3+ cartridge is run, only the pH, PCO_2 and PO_2 measurement channels will be tested (if more than 8 hours have elapsed when set to 8/24 hour operation). If an EG7+ cartridge immediately follows, the internal Electronic Simulator test will be activated again to test the Na, K, iCa and Hct channels (if it has been longer than 24 hours for the electrolytes and/or longer than 8 hours for the hematocrit).

Why does the internal Electronic Simulator activate every 8 hours even for "glucose-only" cartridges when using the 8/24 hour operation?
The Analyzer's software will not yet have determined the cartridge type at the time the internal Electronic Simulator test is run. It must test the amperometric channel (used for both glucose and oxygen) on an8-hour basis to be consistent with the blood gas requirements.

INTERPRETING PASS/FAIL RESULTS

Are the PASS/FAIL limits for the internal Electronic Simulator test the same as for the external Electronic Simulator test?
The test limits are basically the same.

Due to practical considerations, the test levels are a bit different in the internal circuitry compared to the external Electronic Simulator circuitry. Both sets of test levels stress the measurement range. The test limits in both will flag deviations from specifications well before the Analyzer's electronics can contribute an error of clinical significance.

What happens if the internal Electronic Simulator test fails?
The handheld analyzer will display the "Electronic Simulator Fail" message, and the module will display "Internal Simulator Test Failed". In both cases the Analyzer's mechanism is then reset.

Can an Analyzer be used if the internal Electronic Simulator test fails?
Through the customization utility, the Analyzer can be set into one of two modes:

> If "QC lockout" is enabled, the Analyzer will continue to perform the internal Electronic Simulator test each time a cartridge is inserted until an Electronic Simulator test (internal or external) passes. Due to the sensitive nature of the test, it is possible that the test will pass on a second try (as with the external Electronic Simulator test).
>
> If "QC lockout" mode is disabled, the Analyzer will run the next cartridge without performing the internal Electronic Simulator test until the specified time has elapsed.

If the internal Electronic Simulator test fails, can I rerun the cartridge?
The internal Electronic Simulator test is run before the sample testing cycle. The same cartridge can be rerun in the same or another Analyzer if the Electronic Simulator test fails since the sample testing cycle was never activated.

Does a failed test indicate that the Analyzer is out of specification?
The extremely sensitive nature of both the internal and external tests creates the possibility that a spike of noise may cause false test failures once in a while. The cartridge should be rerun to confirm the failure.

The Analyzer's connector pins are in contact with the biosensor chips in the cartridge being tested when the internal Electronic Simulator test is being performed. The test can thus also fail if the contact pads have been contaminated in some way. In this case the Analyzer itself may be operating to specification.

What should I do if a test fails?

1. If "QC lockout" is enabled, rerun the cartridge in the same Analyzer to ensure the FAIL was not due to a one-time spike of electrical noise.
2. If the test fails again, or the "QC" lockout is disabled, rerun the cartridge in another Analyzer if immediately available. Note that the cartridge should not be run if there is more than a three minute delay from the time it is filled.
3. If the cartridge fails in more than one Analyzer, use another cartridge.
4. An external Electronic Simulator can be used to verify proper performance of the Analyzer.

REGULATORY/ACCREDITATION

Does the internal Electronic Simulator test meet regulatory and accreditation requirements for quality control?

The circuitry in the internal Electronic Simulator operates the same way as the circuitry in the external version of the Electronic Simulator. It has the same six key characteristics:

1. It is an independent circuit.
2. The signals it generates simulate the sensitive, high-impedance nature of the biosensors in test cartridges.
3. It qualifies the performance of the Analyzer at levels well below clinical significance.
4. It tests the Analyzer electronics at a minimum of two levels for each measurement channel.
5. The test signals stress the measurement range of the Analyzer well beyond signals generated by the test cartridges.
6. The results of the test are automatically electronically documented.

These are the key characteristics that allow the internal version of the Electronic Simulator to be as appropriate as the external version of the Electronic Simulator for meeting regulatory and accreditation requirements.

THE ROLE OF THE EXTERNAL ELECTRONIC SIMULATOR

Do I need to maintain the external Electronic Simulator?

The external Electronic Simulator can be valuable in the following situations:

1. The external Electronic Simulator tests the Analyzer "on demand". This resets the elapsed time counter so that the internal Electronic Simulator test will not activate for the specified number of hours and ensures minimum sample-testing times.
2. The external Electronic Simulator is required to set the handheld analyzer into a "utility" mode. This mode allows you to clear the handheld analyzer's memory, set the IR print protocol and download software from one handheld to another.
3. The external Electronic Simulator allows you to confirm that a failed internal test may be due to a contaminated cartridge.
4. The external Electronic Simulator is used after a software update or in response to a "SIM" message or a quality check code where the action statement is "Use Electronic Simulator". This is because the internal Electronic Simulator is only triggered by a lapse in time and would not run in response to these.
5. The external Electronic Simulator enables a calibration verification of the thermistors used for thermal control of the fluid. This calibration verification should be performed at least 2 times per year.

i-STAT

TECHNICAL
BULLETIN

Instructions for the Analyzer Customization Profile Utility

for use with the i-STAT® Portable Clinical Analyzer with thermal control 37 and the
Hewlett-Packard M1022A Blood Analysis Module for HP Patient Monitors

Introduction

Features

The Analyzer Customization Profile Utility, in conjunction with the i-STAT Central Data Station, allows:

- creation of customized profiles for i-STAT Portable Clinical Analyzers with thermal control 37 and/or the Hewlett-Packard M1022A Blood Analysis Module for OmniCare CMS Patient Monitors *(collectively referred to as "Analyzer")*. The profiles allow the specification of such items as units for results, the CLEW version and site-specific behaviors such as the calculation used to determine base excess.
- automated profile updates of i-STAT Portable Clinical Analyzers with thermal control 37 with the customization profile. (At this time, profile updates to a Blood Analysis Module are not made automatically. If customization settings are selected which differ from the factory default settings, new or replacement modules must be customized following the instructions contained in this document)

How does it work?

After the customization profile has been created and customization is enabled, the Central Data Station programs the parameters into each Analyzer.

Whenever a handheld analyzer transmits to a CDS, the CDS checks the handheld customization parameters. If they are not current, the CDS updates the handheld analyzer automatically. This ensures that all handheld analyzers are operating with the same customization parameters without having to manually track and configure them individually.

The customization profiles in Blood Analysis Modules are updated by directly connecting the module to the CDS.

If two Central Data Stations are linked together, both with customization enabled, and data are transmitted from one to another, the receiving CDS will check the customization parameters of data coming from the sending CDS. If they are not current, the receiving CDS will update the sending CDS automatically. If multiple CDSs are linked, this will occur successively until all CDSs in the link that have customization enabled are updated. Handheld analyzers will be automatically updated after the CDS to which they transmit is updated.

Note: The Analyzer application software (JAMSXXXX or HPXXXXXX) cannot be updated with this function.

Analyzer Customization Profile Utility Windows

The Language Window

This window allows selection of the language for user prompts and messages on the handheld analyzer only. (The default setting is determined by the Central Data Station market/language.) With the Blood Analysis Module, language is determined by the CMS.

The CLEW Window

This window allows selecting of the i-STAT CLEW that is to be used. A list of all non-expired i-STAT CLEW's currently on your Central Data Station is presented. Reference the most recent i-STAT Product Update and/or labels on i-STAT cartridges to ensure selection of the proper CLEW. (No factory default is selected.)

Note: The CLEW for the module will be different from the CLEW for the handheld analyzer.

Note: If the proper CLEW is not one of the choices, exit the Analyzer Customization Profile Utility and follow the instructions sent with the most recent software update disk to add the CLEW to the list.

The Unit Set Window

This window allows selection of the reporting units for results in modules and handheld analyzers. Choose one of the predefined sets from the list under *Select* (the window called *Analytes* details the units for each analyte in the highlighted set) or choose Unit Set 99 for a set which is user-definable. When Unit Set 99 is selected, a tab called *User Settings* becomes functional. Clicking this tab activates the choices. As each analyte is highlighted, drop-down-list boxes are presented with labels and reporting units for that analyte. Changes are made by highlighting one of the choices. Selections are displayed in the box labeled *Analytes.*

Two analytes have choices for labels. They are Urea or BUN and U/Cre or B/Cre. Use caution when selecting the appropriate label and units.

Click *Factory Default* to select the unit set for which that system was configured on initial purchase. (The default setting is determined by the Central Data Station market/language.)

‼ **Caution:** *Use caution when selecting units as some unit sets affect actual report parameters. Example: Unit Set 00 reports BUN as mg/dL; Unit Set 01 reports this as mmol/L of Urea, and Unit Set 03 reports this as mg/dL of Urea.*

The Preferences Window

This window allows selection of various site-specific behaviors for Analyzers as described below. The selections under the Preferences Window are divided into four tabbed sections. While most behaviors are available for both handheld analyzers and the Blood Analysis Module, others are available for the handheld analyzer only.

DATA ENTRY

Behavior	Description
Patient ID	Select *Minimum length/Maximum length* to specify the minimum and maximum number of digits that the handheld analyzers should accept for Patient ID. Click the arrow in the box after *Minimum length* and make a selection from the list for the minimum number of digits. (The limits are 0–12.) Click the arrow in the box after *Maximum length* and make a selection to determine the maximum number of digits. (The limits are 0–12). If only one fixed length is acceptable for Patient IDs, the minimum and maximum numbers should be the same. To disable this function and allow the Patient ID to be any number of digits, click the circle next to *Allow any length.* An X in the box next to *Repeat ID Entry* programs the handhelds to require the Patient ID to be entered twice. Click in the box to remove the X to allow the Patient ID to be entered only a single time.
Cannot be customized in Blood Analysis Module	(The factory defaults are to allow any length of Patient ID and to require the Patient ID to be repeated during the ID entry.)
Operator ID	Select *Minimum length/Maximum length* to specify the minimum and maximum number of digits that the handheld analyzers should accept for Operator ID. Click the arrow in the box after *Minimum length* and make a selection from the list for the minimum number of digits. (The limits are 0–12.) Click the arrow in the box after *Maximum length* and make a selection to determine the maximum number of digits. (The limits are 0–12). If only one fixed length is acceptable for Operator IDs, the minimum and maximum numbers should be the same. To disable this function and allow the Operator ID to be any number of digits, select *Allow any length.* An X in the box next to *Repeat ID Entry* programs the handhelds to require the Operator ID to be entered twice. Click in the box to remove the X to allow the Operator ID to be entered only a single time.
Cannot be customized in Blood Analysis Module	(The factory defaults are to allow any length of Operator ID and to require the Operator ID to be repeated during the ID entry.)
Auto-Chart Presentation *Cannot be customized in Blood Analysis Module*	Select *On* to force the data entry page to appear automatically after the Patient ID number is entered the second time. Select *Off* to disable this feature. When disabled, the operator must press the **PAGE** key on the analyzer to display the data entry page. (The factory default is Off.)
Operator Test Selection	Select *On* to enable the handheld analyzer to allow the operator to select the tests to be reported (and thus billed) from the tests available on a cartridge. Select *Off* to disable this feature.
Cannot be customized in Blood Analysis Module	For assistance with using this option, refer to the i-STAT Technical Bulletin "Operator Test Selection". (The factory default for Operator Test Selection is Off.)

Behavior	Description
Patient ID Recall *Cannot be customized in Blood Analysis Module*	Select *On* to enable the handheld analyzer to allow the DIS key to recall the last Patient ID in memory as the Patient ID for the current cartridge being analyzed. Select *Off* to disable this function. When this function is enabled in a handheld analyzer, the operator would press the DIS key when the handheld analyzer is prompting for the entry of the Patient ID. The most recent Patient ID would be displayed in the ID space. After pressing the ENT key, the operator would repeat this step if the "Repeat ID Entry" is also enabled. (The factory default for Patient ID Recall is On.) ! **Caution:** : i-STAT recommends this function be used cautiously, perhaps only by those departments, such as a surgery area, where a handheld analyzer is dedicated to only one patient for an extended period of time.
i-STAT Reserved	This field is currently not active and is reserved for future customization options.

SIMULATOR

Behavior	Description
External Electronic Simulator Reminder	Select how soon after an external Electronic Simulator is run that the Reminder message should appear to prompt the user that it is time to run the external Electronic Simulator again. Select *Off* to prevent the reminder message from appearing. (The factory default is determined by the CDS market/language.)
Internal Simulator	Select how often the internal Electronic Simulator should be run. Select *Off* to prevent the internal Electronic Simulator from ever running. Select *8/24 Hour Schedule* to run the internal Electronic Simulator every 8 hours for pH, PCO_2, PO_2 and hematocrit channels and 24 hours for all other channels. Select "*On at ...*" to run the internal Electronic Simulator at the interval selected from the list. The i-STAT Technical Bulletin "i-STAT Internal Electronic Simulator" can provide guidance. (The factory default is Off.)
QC Lockout	Selection of this setting prevents analyzers from running a cartridge after a failed internal Electronic Simulator test. (The factory default is QC lockout disabled.)

REPORTED VALUES

Behavior	Description
Reported Values	Any value marked with an X will be reported when a cartridge capable of reporting that value is analyzed. To disable reporting a value, click the box next to the value to remove the X. To re-enable a value, click the box next to the value to place an X. Click *OK* when finished. (The factory default is all values reported.)
Decimal Separator *Cannot be customized in Blood Analysis Module*	Select whether a period or comma should be used as the decimal separator in results. (The factory default is determined by the CDS market/language.)

COMPUTATIONS

Behavior	Description
Hematocrit Reference Anticoagulant	Select **K_3EDTA** for i-STAT hematocrit values standardized to the centrifugal microhematocrit method using K_3EDTA as the anticoagulant. Select **K_2EDTA/Heparin/None** for i-STAT hematocrit values standardized to the centrifugal microhematocrit method using either K_2EDTA, heparin or no anticoagulant. The i-STAT Technical Bulletin "Hematocrit Determination in the i-STAT System and Comparison to Other Methods" can provide guidance. (The factory default is K_3EDTA.)
Base Excess Calculation	Select the calculation to be used for reporting base excess — either extracellular fluid or whole blood. (The factory default is extracellular fluid.) The choices for calculations are: **extracellular fluid**: $BE_{ecf} = HCO_3 - 24.8 + 16.2\ (pH - 7.4)$ *or* **whole blood**: $BE_{bld} = (1 - 0.014Hb)(HCO_3 - 24.0 + (1.43Hb + 7.7)\ (pH - 7.4))$
Report Hct, CPB Always *Cannot be customized in Blood Analysis Module*	Select *On* to program handheld analyzers to report all hematocrit and hemoglobin from cartridges analyzed on those handheld as if CPB (cardiopulmonary bypass) was selected for the sample type on the chart page. Select *Off* to disable this function. The i-STAT Technical Bulletin "Hematocrit Determinations using the i-STAT System During Cardiopulmonary Bypass Procedure" can provide guideance (The factory default is Off.)
i-STAT Reserved	These fields are currently not active and are reserved for future customization options.

Note: To return all settings to their i-STAT default values, click Factory Default.

Enabling Customization

Two ways to enable customization

There are two ways to enable customization:
- by creating a profile
- by restoring a backup file

To create a profile

Following are the steps necessary to define the customization profile. These steps also enable the CDS to automatically update handheld analyzers:

Step	Action
1	Exit the Central Data Station Application and return to the Program Manager.
2	In the i-STAT CDS program group, double click the Customization Utility icon.
3	The Enter Password screen is presented. The initial password is **istat**. Once customization is enabled, the password should be changed as described in the section "Changing the Utility Password".
4	When customization is disabled, the Enable Analyzer Customization screen is presented with three choices: *Setup Mode* enables customization by allowing creation of a customization profile. *Restore* enables customization by restoring a saved customization profile. *Cancel* exits the program without enabling customization. To proceed with creating a customization profile, click *Setup Mode.*
5	A series of windows is presented where parameters are defined. In each window, make a selection and then click *Next.* In the final window, click *Finish.* (Reference the section of this document titled "Analyzer Customization Profile Utility Windows" for explanations of parameters.) **Note:** Click *Previous* in any window to return to the previous window. **Note:** Click *Factory Default* in windows where available to default the selection to the factory default setting for that parameter. Default settings are listed in the "Analyzer Customization Profile Utility Windows" section of this document. **Note:** Click *Cancel* in any window, then confirm cancellation by clicking *Yes,* to abort the entire definition process and exit the program. **Customization will not be enabled.**
6	When *Finish* is clicked, all settings are saved and a window showing current settings is presented. Exit the utility be selecting **Exit Program** under the **File** menu item in the menu bar or press CTRL-X.
7	Restart the Central Data Station Application

To restore a backup file

Note: See the section of this document titled "Making a Backup of the Customization Profile" for instructions on making a backup file.

Following are the steps necessary to restore a backup profile:

Step	Action
1	Exit the Central Data Station Application and return to the Program Manager.
2	In the i-STAT CDS program group, double click the Customization Utility icon.
3	The Enter Password screen is presented. The initial password is **istat**. Once customization is enabled, the password should be changed as described in the section "Changing the Utility Password".
4	When customization is disabled, the Enable Analyzer Customization screen is presented with three choices: *Setup Mode* enables customization by allowing creation of a customization profile. *Restore* enables customization by restoring a saved customization profile. *Cancel* exits the program without enabling customization. To proceed with restoring a profile, click *Restore*.
5	Click the appropriate file name or enter the name of the backup file in the box under **File Name**. Click *OK*. Follow the instructions on the screen.
6	When *Restore* is complete, all settings are saved and a window showing current settings is presented. Exit the utility by selecting **Exit Program** under the **File** menu in the menu bar or press CTRL-X.
7	Restart the Central Data Station Application.

To restore profile to another CDS

The steps under "To restore a backup file" can also be used to transfer a customization profile to another CDS.

Updating the Profile in a Handheld Analyzer

‼ **Caution:** Before updating the customization profile in the handheld analyzer or module, be sure the CLEW selected is correct for the analyzer type. Refer to the Product Update which accompanied the most recent software update disk for instructions.

To update profile in a handheld analyzer

When customization is enabled, each handheld analyzer will be automatically programmed with the customization profile settings after it transmits results to the Central Data Station. The CDS will continually monitor handheld analyzer transmissions and ensure each one is using the proper settings.

Handheld analyzer display

On the handheld analyzer Status Page, the **Unit** Set is displayed as Unit, the CLEW as **CLEW**, and the Preferences as **Cfg**. (Reference the section of this document titled "Analyzer Customization Profile Utility Windows" for explanations of parameters.)

Updating the Profile in a Blood Analysis Module

⚠ **Caution:** Before updating the customization profile in the handheld analyzer or module, be sure the CLEW selected is correct for the analyzer type. Refer to the Product Update which accompanied the most recent software update disk for instructions.

To update profile in a module

Following are the steps to update the customization profile in the Blood Analysis Module:

Step	Action
1	Reconfigure port assignments in the Central Data Station as follows: (Instructions for this procedure can be found in the Central Data Station section of the i-STAT System Manual under "Configuration & Data Backup".) ▪ Make a note of how each of the COM ports is currently configured. ▪ Configure one of the ports (typically COM5) currently set as "Analyzer" to "Module". (In the CDS software version which allows customization, five choices are available on the screen for configuring port assignments: Off, Analyzer, Module, CDS, Send.) ▪ Configure all other ports currently set as "Analyzer" or "CDS" to "Off". **Note:** *Reconfiguration of these ports will disallow transmissions of data from all Analyzers while the downloading of customization profiles into modules is taking place. If IR Links are in use in the system, all lights will be red.*
2	Connect a Modular Data Cable to the port on the CDS configured for the module. A section of cable normally used to connect an IR Link to the CDS can be used if available.
3	Restart the Central Data Station Application.
4	With Customization enabled and the CDS software running, attach the opposite end of the cable to the port on the back of the module. Attaching the cable to the module initiates the downloading of the customization profile to the module. This takes approximately 45 - 60 seconds -- DO NOT DISCONNECT THE MODULE DURING THIS TIME.
5	The downloading of the customization profile can result in one of three possible combinations of beeps from the CDS: ▪ One short beep means the CDS found the customization profile in the module needed no updating. ▪ Three short single beeps occurring over approximately 20 - 30 seconds mean the updating of the customization profile was successful. ▪ Five beeps in quick succession mean the updating was not successful. Unplug the cable from the module and try again.
6	To update the customization profile in another Blood Analysis Module, repeat this procedure from Step 4.

7 When all module updates are complete, restore the CDS to normal function as follows:

- If Customization is to remain enabled to perform automatic updates on handheld analyzers, edit the customization profile as appropriate for handheld analyzers or restore an appropriate backup file using the instructions found in this section.
- If automatic updates of handheld analyzers is not preferred, see the section of this document titled "Disabling Customization" for instructions on disabling this function.
- Reconnect any IR Links which may have been disconnected.
- Return the configuration of the CDS port assignments, edited in Step 1, to their original status.
- Restart the CDS Application.

CMS display for module

The CLEW version is displayed on the Blood Analysis Setup screen of the CMS. To verify other customization parameters downloaded into the Blood Analysis Module, see the section of this document titled "Viewing Customization Settings from the CDS Application".

Changing Customization Profile when Customization is Enabled

Changing a customization profile

The customization profile can be changed two ways:

- by editing the current customization profile
- by restoring a backup file

To edit current profile

Following are the steps necessary to edit a customization profile when customization is enabled:

Step	Action
1	Exit the Central Data Station Application and return to the Program Manager.
2	In the i-STAT CDS program group, double click the Customization Utility icon.
3	When prompted, enter the password and click *OK*.
4	The customization profile utility main window is presented with the Current Analyzer Customization Profile displayed.
5	To change a setting, click the button displaying the current setting or select the setting under the Customize menu item in the menu bar or press the hot key for that item.
6	The window for the setting is presented. Make selections and then click Save Selection. (Reference the section of this document titled "Analyzer Customization Profile Utility Windows" for an explanation of parameters.) **Note:** The Preferences setting is displayed on the main window as a name. The utility automatically assigns a unique name to the combination of setting for parameters contained in Preferences. **Note:** Click Cancel in any window to leave the setting unchanged and return to the main customization window.
7	When all settings are as desired, exit the utility by selecting **Exit Program** under the **File** menu item in the menu bar or press CTRL-X.

	Note: Each customization setting—Language, Unit Set, CLEW, and Preferences—is saved separately when *Save Selection* is clicked in the corresponding window. There is no final "Save Selection" action required. Then main customization profile utility window always shows the current settings.
8	Restart the Central Data Station Application.

To restore a backup profile

Following are the steps to follow to restore a backup profile:

Step	Action
1	Exit the Central Data Station Application and return to the Program Manager.
2	In the i-STAT CDS program group, double click the Customization Utility icon.
3	When prompted, enter the password and click *OK*.
4	The customization profile utility main window is presented with the Current Analyzer Customization Profile displayed Select **Restore Profile**...under the **File** menu item in the menu bar. Click the appropriate file name or enter the name of the backup file in the box under **File Name**. Click *OK*. Follow the instructions on the screen.
5	When *Restore* is complete, all settings are saved and a window showing current settings is presented.
	Exit the utility by selecting **Exit Program** under the **File** menu in the menu bar or press CTRL-X.
6	Restart the Central Data Station Application.

Making a Backup of the Customization Profile

To backup the profile

To make a backup of the customization profile created, follow the steps below:

Step	Action
1	From within the customization profile utility main window, select **Backup Profile**...under the **File** menu item in the menu bar.
2	In the box under **File Name**, replace the * with the selected name (8 characters or less). Do not change the **.acp** extension. Click *OK*.
3	Click OK again after the window states the backup file was written successfully.

Disabling Customization

To disable customization

In some institutions, handheld analyzers in different departments may need to be customized with different settings. When this is the situation, customize handheld analyzers as necessary, then disable customization so that automatic updating does not occur.

Follow these steps to disable the automatic updating of Analyzers to the current customization settings:

Step	Action
1	Exit the Central Data Station Application and return to the Program Manager.
2	In the i-STAT CDS program group, double click the Customization Utility icon.
3	When prompted, enter the password and click OK.
4	**Note:** A backup of the customization settings should be made prior to disabling customization. To make a backup, reference the section of this document title "Making a Backup of the Customization Profile" for instructions. Select **Disable Customization** under the **File** menu item in the menu bar. Click *OK* to confirm.
5	Restart the Central Data Station Application.

! **Caution:** When customization is disabled, all Analyzers will remain configured as they were at the time customization was disabled. If customized settings were selected which differ from the factory default settings, new or replacement Analyzers must be customized by enabling customization, transmitting results from the analyzers to the CDS, and then disabling customization.

Changing the Utility Password

To change the password

Select **Change Password** under the **System** menu item on the menu bar. Follow the instructions on the screen.

Click *OK* to accept the change or *Cancel* to exit the screen and make no changes to the password.

Note: The password must be at least three characters long but not more than eight characters.

Remember: Record the password in a safe location for future reference!

Troubleshooting

Password unknown

If the password is not known, call your technical support provider for assistance.

Error screen

If the utility detects any errors that prevent it from running, an error screen is presented at startup. The screen indicates the error condition. If the error condition is not clear or the indicated problem cannot be corrected, contact your technical support provider.

No beeps after plugging cable into module

If the Module LEDs are off, possibly the cable or the COM port is defective. Try another cable and/or configure a different port to "Module" and try again.

If the Module LEDs are on, possibly the cable is defective or the COM port is not configured properly. Try another cable and/or ensure the configuration of the COM port being used is set to "Module". If condition persists, there may be a module error. Insert the module into a COM and run the External Simulator. If Simulator test fails, try connecting another module.

Viewing Customization Settings from the CDS Application

Customization settings

To view current customization settings, select **System**, then **Customization**, then **Analyzer**...

Preference settings

To view preference settings for the highlighted record, select **Records** and then **Preferences**...or press F5.

i-STAT

TECHNICAL BULLETIN

Operator Test Selection

Operator Test Selection is a customizable feature for i-STAT® Portable Clinical Analyzers with thermal control. When enabled, the operator is required to choose specific tests from those available whenever a cartridge is analyzed. It is enabled using the Analyzer Customization Profile Utility on the Central Data Station.

How does it work?

1. After the cartridge is inserted into the handheld analyzer, the Operator and Patient IDs are requested and entered.
2. After "CONTACTING CARTRIDGE" disappears, the operator is presented with a list of the available measured tests on the cartridge being analyzed, each with a number beside it.
3. The operator can select any single or multiple tests by pressing the appropriate keys for the numbers or "0" for all available tests. Selection of a test will reverse video (dark background, light lettering) the number beside it. To deselect a test, press the appropriate key to return the number to the light background.
4. The **PAGE** key is pressed to move to the next page.
5. The chart page is displayed automatically and patient information is entered.
6. The **PAGE** key is pressed to move to the next page.
7. Results are displayed only after all data entry is complete.
8. Only the selected results will be shown on the analyzer display. Tests available on the cartridge that were not selected will be displayed as the name of the test with no result and an empty bar graph, if appropriate.

Can changes be made to the test selection?

Additional tests can be selected or deselected until the results are displayed on the screen. At that point, tests not previously selected can be added to the list, but, once viewed, no test can be deleted from the list

What if no tests are selected?

If no tests are selected and results are ready, the analyzer will report "Results Ready". Once IDs are entered, the selection page is displayed and choices can be made. If another cartridge or the Electronic Simulator is inserted into the analyzer, or if the record is printed or transmitted before any tests are selected, the record is stored with all results blank.

What results are transmitted?

Only the selected results will be transmitted and displayed on the Central Data Station.

How does this affect the AME interface?

If the AME interface is currently used to determine panels in the LIS/HIS, turning on Operator Test Selection may affect the customization of the interface. If you need changes to the AME interface or if you need help determining if changes are required, contact your interface provider.

i-STAT

TECHNICAL BULLETIN

Incompatibility between the i-STAT System and SIMS Line Draw Syringes

i-STAT Corporation and SIMS Portex Inc. have determined that there is a potential for sporadic, artificially low *P*CO2 results on the i-STAT® System when measuring blood collected with either SIMS Portex **Dry Line Draw®** arterial blood gas sampling syringes with dry lithium heparin or SIMS Portex **Anaerobic Line Draw®** arterial blood gas sampling syringes with liquid sodium heparin.

All i-STAT users, worldwide, who purchase SIMS Portex sampling syringes, should contact SIMS Portex Inc., Keene, NH, USA (Telephone 603-352-3812) and identify yourself as an i-STAT System user to ensure that you receive only compatible syringes for use with the i-STAT System.

This document obsoletes previous revisions of this Technical Bulletin.

Important Notice

i-STAT is a registered trademark of i-STAT Corporation.
Dry Line Draw is a registered trademark of SIMS Portex Inc.
Anaerobic Line Draw is a registered trademark of SIMS Portex Inc.

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P/N: 014268-00 01A Art: 714268-00 A Rev. Date: 04/16/01

i-STAT

TECHNICAL BULLETIN

i-STAT Central Data Station (for Windows) Utilization

The Utilization program is a tool in the Central Data Station which provides information that may be useful in the administration of the i-STAT® System. It includes information on cartridge utilization and occurrence of quality check codes. This Technical Bulletin provides instructions for using the Utilization program.

How to access

To access summary reports for all data currently in the Central Data Station database, double click on the Utilization icon in the i-STAT CDS program group.

It is not necessary to exit the CDS application when running Utilization. This allows the CDS to continue receiving data while reports are being generated. Please note, however, the Utilization Reports will be snapshots of the database at the time the utility is started and are not updated real time.

Information Produced

The **i-STAT Monthly Totals** report shows:

- number of cartridges used per month
- number of quality check failures detected
- number of simulator results
- totals for the above

Three Additional Reports

Three additional reports provide greater detail:
Double click on the desired month to view the **System Usage Report**.
It displays:

- the number of results produced for each cartridge type by location
- the total number of results produced at each location
- the number of quality check failures at each location
- the percentage of quality check failures to the total number of cartridges used at each location
- totals for each of the above
- To view either of the others, click on the *Select Report* button and make a choice of the available reports.

The **System QC Codes by Location Report** displays:

- the percentage of quality check failures to the total number of cartridges used at each location
- the number of quality check code failures occurring in each location, grouped by code type
- totals for each type of quality check code

The **System QC Codes by Operator Report*** displays:

- a list of operators that have generated three or more quality check codes in the month
- the total number of results produced by each of these operators
- the number of quality check codes for each of these operators grouped by type
- totals for each type of quality check code

Click *Select Report* to choose between the System Usage Report, the System QC Codes by Location Report, and the System QC Codes by Operator Report.

Click *Return* to return to the i-STAT Monthly Totals screen.

Location Identification and Grouping

For easier use of the reports generated in **Utilization**, locations can now be identified by name. For example, the ICU, which may have been previously identified as Location 5, can now be renamed as ICU.

Additionally, multiple locations in the same department (multiple IR Links and/or multiple HP Blood Analysis Modules) can now be grouped together under one name. This allows the "System Usage" and "System QC Codes by Location" reports to provide more useful statistics for a particular department or unit.

How to use:

- To edit location names or groupings, click *Location* from the **i-STAT Monthly Totals** screen of **Utilization.**
- If data has been received from a location, it will appear automatically in the **i-STAT Monthly Totals – Location Screen** with the location name and the location code the same.
- The Location Name can be edited as desired (maximum 10 characters) for easier identification.
- Locations from which no data has been received can be added manually by clicking *Add location.* Once data has been received from a location, that location cannot be deleted.
- Different location codes with the same Location Name will automatically become one group.

New groups can be made and existing groups can be edited by clicking *New Grouping* or *Edit Grouping,* then highlighting the appropriate location code and using *Add* or *Remove* as desired.

Printing

To print any of the reports, click on the *Print* or *Print this report* button while the report is displayed on the screen.

* To access the report, it must first be activated. Simple instructions are included below to activate this additional report.

Instructions for Activating the Report

If your CDS operates on Windows Version 3.1

1. Exit the CDS program by clicking on the Exit button on the lower right corner of the screen.
2. At the Program Manager click on the Utilization icon.
3. Select File from the menu bar.
4. Click on Properties. The following information should appear on your screen. You will need to add the letters fullstatcon after mtotals.exe in the second line as seen below.

Description:	Utilization
Command Line:	c:\istatcds\bin\mtotals.exe fullstatcon
Working Directory:	c:\istatcds\bin
Shortcut Key:	none

5. Select OK. The additional report will be available in the Utilization program.

If your CDS operates on Windows Version 95 or 98

1. Select Start, then Settings from the lower left corner of the screen.
2. Click on Taskbar & Start Menu. Select the "Start Menu Programs" tab.
3. In the "Customize Start menu" box, select Advanced.
4. Open the "Programs" folder in the "Start Menu" folder on the left side of the screen.
5. Double click on "i-STATCDS" from the right side of the screen.
6. Right click the mouse on "Utilization" from the right side of the screen. Select Properties at the bottom of the drop down box.
7. Select the "Shortcut" tab from Utilization properties, The following information should appear on your screen. You will need to add the letters fullstatcon after MTOTALS.EXE in the top line as seen below.

Target:	c:\istatcds\bin\MTOTALS.EXE fullstatcon
Start In:	c:\istatcds\bin
Shortcut Key	None
Run:	Normal window

8. Select OK. The additional report will be available when the Utilization program is started.

i-STAT

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Installation Guide for the Central Data Station to Receive Data from a Patient Data Server

The i-STAT Central Data Station (CDS) application can be configured to receive results from cartridges analyzed on a Blood Analysis Module (BAM), as part of a Hewlett Packard CMS Patient Monitor System. This data is sent to the CDS by the HP Patient Data Server (PDS). This document describes how to set up the i-STAT CDS application to receive data from the HP PDS. It is independent of the computer hardware platform being used.

Configuration Instructions

This guide assumes that the PDS connectivity to the location of the CDS computer is completed, and that the PDS data is available via one of these two protocols:

- A direct RS-232 serial connection
- An Ethernet connection to a ETS 8 Terminal Server (CDS 4.x) or a Network Interface Card (CDS5.x)

To configure the CDS 5.x:

Step	Action
1	Run the CDS application (wcds32.exe) with the “config” command line parameter.

The remainder of the configuration is dependent on the connection of the PDS to the CDS.

For PDS data received via a direct RS-232 connection:	
2	Determine which COM Port of the CDS computer is to be used for the PDS data.
3	At the Serial Ports tab page, select *“Enable Serial Communications”*. Add the COM Port to be used for the PDS to the *“Configured Ports”* list, select Agilent PDS as instrument type, and click *“Accept”*.
4	Connect the cable to the appropriate COM Port on the CDS computer.
5	Verify that the PDS data is being received.

For PDS data received via an ETS 8 Terminal Server:	
2	At the Network tab page, select *“Enable Network Communications”*. Note the default TCP port of 6002, change if neccessary. And click *“Accept”*.
3	Verify that the PDS is configured to transmit to the specific port noted in step 2 at the CDS IP network address.
4	Verify that the PDS data is being received.

To configure the CDS 4.x:

Step	Action
1	Determine which COM Port of the CDS computer is to be used for the PDS data.
2	Using the Configuration Utility of the CDS, change the data source of this COM Port to the “CDS” option.
3	Exit the Configuration Utility.

The remainder of the configuration is dependent on the form of the PDS data.

	For PDS data received via a direct RS-232 connection:
4	Determine the communication speed of the PDS. Ideally, it should be set at 19200 baud.
5	• If set to 19200, use any text editor to edit the file C:\istatcds\istatcfg.txt. Add the following line to the section with the heading of **[Options]:** **FastCdsSend=YES** Save the file and exit the Text Editor. • If set to 4800, no changes are needed
6	Connect the cable to the appropriate COM Port on the CDS computer.
7	Verify that the PDS data is being received.

	For PDS data received via an ETS 8 Terminal Server:
4	Determine which serial port on the ETS 8 will be used for the PDS transmission.
5	Verify that the PDS is configured to transmit to that specific port at the ETS 8 Ethernet address
6	Verify that the port of the ETS 8 is configured for 19200 baud.
7	Using any text editor, edit the file C:\istatcds\istatcfg.txt. Add the following to the section with the heading of **[Options]:** **FastCdsSend=YES** Save the file and exit the Text Editor.
8	Connect the cable from the selected ETS 8 serial port to the selected COM port on the on the CDS computer.
9	Verify that the PDS data is being received.

i-STAT

TECHNICAL BULLETIN

SYMBOLS USED IN i-STAT LABELING

Symbols can be helpful in reducing the necessity for translating important information into multiple languages, particularly where space is limited. i-STAT has adopted a number of the symbols accepted by the European Committee for Standardization for medical devices for use on its packaging and in user documentation.

The meaning of some of these symbols is self-evident, in widespread use, and familiar to health care professionals. The meaning of others will become clear, with use or when viewed in the context of the device itself.

The following table details the use of symbols in i-STAT labeling:

⚠	Attention See instructions for use.
🌡	Temperature limitations. The upper and lower limits for storage are adjacent to upper and lower arms.
⌛	Use by or expiration date. The adjacent date, expressed as four digits for the year and two digits for the month, indicates the product should not be used after the end of the month shown. (*See note below*).
LOT	Manufacturer's lot number or batch code. The lot number or batch will appear adjacent to this symbol.
REF	Catalog number, list number, or reference number. The number adjacent to this symbol is used to reorder the product.
SN	Serial number. The number is accompanied by the manufacturer's serial number.
🏭	Date of manufacture.
IVD	*In vitro* diagnostic medical device.

NOTE: i-STAT Corporation will start using the date format stated in the European Standard for the expiration date on its cartridge products. The expiration date will be expressed as YYYY-MM and means the last day the product can be used is the last day of the month given.

For example, a product labeled

⌛ 2001-05

has an expiration or "use by" date of 31 May 2001.

Reference: EN980 May 1996 published by CEN. Ref No. En980:1996E and from European Diagnostic Manufacturers Association Standards News 2. 10 December 1999. www.edma-ivd.be

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QUALITY CONTROL AND THE i-STAT ACT TEST SYSTEM

BACKGROUND

The Quality Control section of the i-STAT® System Manual describes the i-STAT Quality System and how it is designed to meet the unique characteristics of a unit-use testing system. Traditional liquid quality control is not an effective tool for unit-use test devices. Instead the i-STAT Quality System centers on tests automatically performed on each cartridge. As an example, the analyzer's software qualifies each sensor for its intended use. It ensures the sensors behave as expected as they wet up when initially exposed to the calibrant solution packaged on each cartridge.

OPERATING PRINCIPLES OF THE COAGULATION CARTRIDGE – OVERVIEW

The Celite® ACT cartridge measures the time required for complete activation of the coagulation cascade once initiated by the Celite activator. Coagulation instruments determine this time by sensing a characteristic change in a measured property of the sample. In the i-STAT System the measured property is the concentration of an electroactive marker[1]. The time to clot is indicated by a relative increase in the concentration as measured by an amperometric sensor.

i-STAT dries the Celite activator and a precursor of the electrochemical marker (a substrate to the thrombin enzyme produced by the coagulation cascade) onto the wall of the reaction chamber during the manufacturing process. At the beginning of the test the system agitates the blood back and forth across the chamber wall to mix these reagents into the blood sample.

QUALITY SYSTEM FOR COAGULATION CARTRIDGE

The critical performance feature of the coagulation cartridge centers on the repeatability of the reagent mixing process. The accuracy to which the reagent is mixed into the blood sample directly impacts the accuracy of the result.

The system quantitatively confirms the accuracy of the mix by using the amperometric sensor to measure the concentration of the "precursor" substrate[2] in the blood. This quality test is performed on each coagulation cartridge.

i-STAT's microfabrication production processes are inherently capable of creating sensors with highly reproducible characteristics. For the measurement of blood gases, electrolytes and chemistries, this means that the i-STAT System requires only a one-point calibration, using a calibrant solution packaged in the cartridge, to meet the demanding requirements for clinical accuracy. As described in the Quality Control section of the i-STAT System Manual, the calibrant solution is also used to verify the integrity of the sensors as a key component of the quality system.

For the measurement of ACT, the required accuracy for the amperometric sensor to detect the relative increase in concentration of the electroactive marker is more modest. A calibrant solution is required neither for a one-point calibration nor to verify the wetup characteristics of the sensor. Instead, the quantitative measurement of the concentration of the substrate in the blood is used to verify the integrity of the sensor as well as the quality of the mix.

REGULATORY ASPECTS OF THE QUALITY SYSTEM FOR COAGULATION

Alternatives to traditional quality systems have been developed that are suitable for ensuring the performance of unit-use in-vitro diagnostic systems. These alternative systems rely upon a variety of internal self-tests and electronic/optical checks. As unit-use devices have become more widespread in clinical practice, regulations and guidance documents have adapted to recognize the effectiveness of these alternative quality systems, albeit with some variation. For example, some state regulations require that the alternative quality system include an on-board "wet" control. The i-STAT Quality System for the coagulation test is able to address this requirement even though the cartridge does not contain an on-board wet calibration fluid. The quantitative confirmation that the Celite activator and the marker are accurately mixed into the blood sample is a "wet" test that acts as a control of the most critical aspect of the coagulation test.

ELECTRONIC QUALITY CONTROL

i-STAT's electronic simulator (both the internal and external versions) check the amperometric and conductivity circuitry used in the coagulation tests at multiple levels. The instrument checks the accuracy of the measurement of elapsed time each time a test is run by comparing the clock rates from two independent clocking circuits. The instrument also runs a battery of general instrument checks during each test.

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[1] The electroactive marker, MeOPADA, is created when the thrombin enzyme produced by the coagulation cascade cleaves the artificial substrate Phe-Pip-Arg-MeOPADA that is mixed into the sample at the beginning of the test.

[2] The precursor Phe-Pip-Arg-MeOPADA is itself moderately electroactive – the system is able to measure its concentration electrochemically by applying a larger potential to the amperometric electrode. During the actual testing phase the system uses a lower potential to be sensitive only to the cleaved electroactive marker.

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Celite is a registered trademark of Celite Corporation, Santa Barbara, CA for its diatomaceous earth products.

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TECHNICAL BULLETIN

BLOOD GAS CARTRIDGES: SHORTENED EQUILIBRATION TIME

i-STAT Corporation's commitment to product improvement has resulted in shortened equilibration times for cartridges which perform blood gases. Because of modifications that improved the equilibration mechanism in these cartridges, all cartridges can now be used after being at room temperature for only 5 minutes for a single cartridge in a pouch or for 1 hour for a box of 25.

The "Preparations for Use" instructions found on page CTI-1 of the Cartridge and Test Information section of the i-STAT® System Manual will be modified to read:

> Individual cartridges in pouches may be used after standing 5 minutes at room temperature. An entire box of 25 should stand at room temperature for one hour.

If you have any further questions about this change, please contact your i-STAT support provider.

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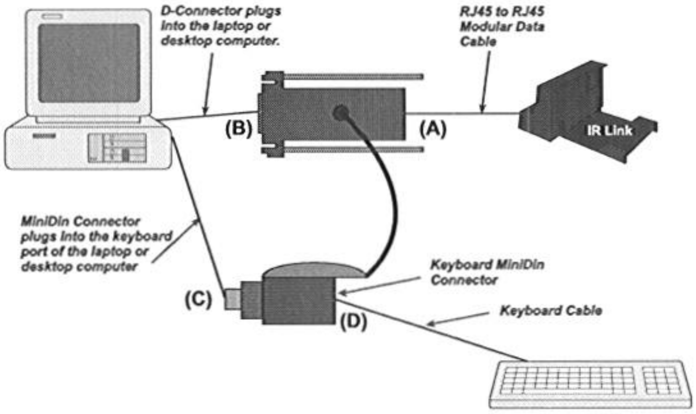
UPDATING ANALYZER SOFTWARE: *NEW* JAMMLITE UTILITY

The new JammLite Utility must be used to update software in the i-STAT®1 Analyzer and can be used to update the i-STAT Portable Clinical Analyzer with thermal control 37 and the Blood Analysis Module. The JammLite procedure is simple with just one screen for all analyzer types and software versions.

To use this utility, you must have a Central Data Station or a computer with Windows® 98 or higher.

	Step	Action
Save the Analyzer Data	1	Download data from the i-STAT Portable Clinical Analyzers before an application update since all data will be erased during the update procedure. Data is not erased from the i-STAT 1 Analyzer.
Shut Down All Programs	2	If the Central Data Station application is running on the computer, disable Customization and exit the CDS application. If using another computer, exit all applications.
Connect IR Link and/or Downloader	3	A COM port connection is required for the software update. IR Link connection: • If using a Central Data Station 5 or higher, connect the IR Link to a COM port using an i-STAT Software Update kit as illustrated below. • If using a Central Data Station 4.04b or c, connect a Modular Data Cable to COM 5 on the back of the CDS. If updating Portable Clinical Analyzers, connect an IR Link to the opposite end of the cable. • For other computers, connect the IR Link to a COM port using an i-STAT Software Update kit as illustrated below.  D-Connector plugs into the laptop or desktop computer. RJ45 to RJ45 Modular Data Cable (B) (A) IR Link MiniDin Connector plugs into the keyboard port of the laptop or desktop computer Keyboard MiniDin Connector (C) (D) Keyboard Cable Blood Analysis Module Connection: The Blood Analysis Module is connected directly to a COM port. Downloader or Downloader/Recharger connection: Connect a serial Downloader or serial Downloader/Recharger to a COM port and plug the power adapter into a wall outlet.

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Copy the Files

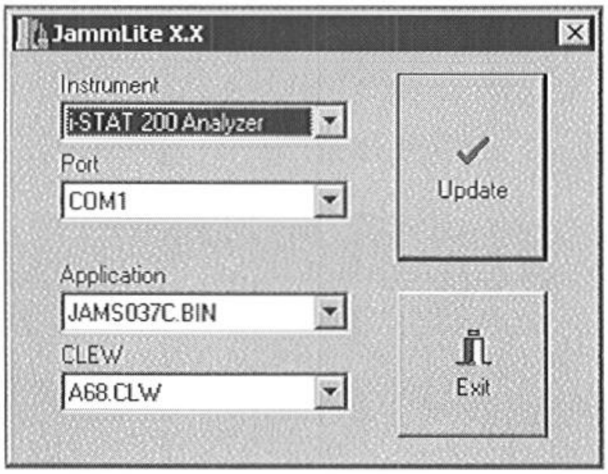
4 Access a DOS prompt on the computer. (Click **Start,** then **Run**...and type **command** into the box provided.)

5 Place the diskette labeled "Software for Analyzers" into the A:drive.

6 At the C:\> prompt, type **A:transfer** and press the Enter key.

Using the JammLite Utility

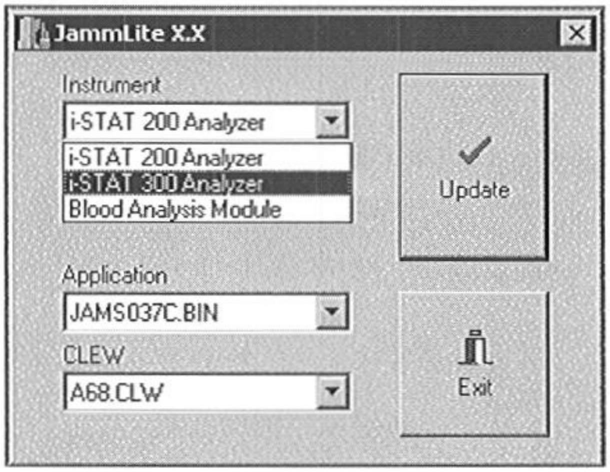
7 At the C:\>bins prompt, type **jammlite** and press the Enter key. The following screen will be displayed:


JammLite X.X
Update
Exit

Instrument: i-STAT 200 Analyzer
Port: COM1
Application: JAMS037C.BIN
CLEW: A68.CLW

X.X is the current version of JammLite softare.

8 Select the appropriate instrument from the Instrument drop-down list.


JammLite X.X
i-STAT 200 Analyzer
i-STAT 300 Analyzer
Blood Analysis Module
Update
Exit

Instrument: i-STAT 200 Analyzer
Application: JAMS037C.BIN
CLEW: A68.CLW

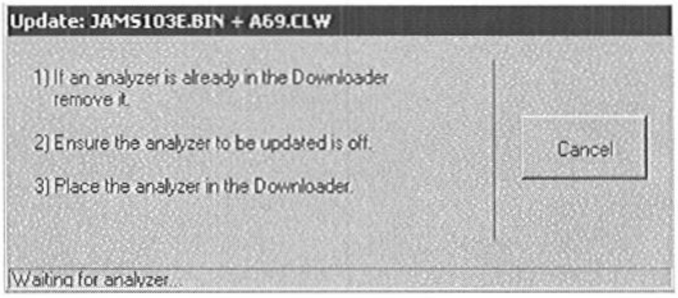
i-STAT 200 Analyzer is the Portable Clinical Analyzer with thermal control and the i-STAT 300 Analyzer is the i-STAT 1 Analyer.

9 Select the COM port for instrument being updated from the Port drop-down list. The JammLite software will list the available COM ports on the computer.

10 Select the appropriate Application and CLEW from the Application and CLEW drop-down lists. Refer to the update package for the correct Application and CLEW. If the update is for CLEW only, select None for Application. Note that there are different application versions for the i-STAT 1 Analyzer and the Portable Clinical Analyzer/Blood Analysis Module. JammLite will display all application software and CLEW appropriate for the instrument that have been loaded on the computer.

11 Click on the Update button to start the update. Appropriate instructions will be displayed. Follow the directions on the screen.

For the i-STAT 1 Analyzer:



Update: JAMS103E.BIN + A69.CLW

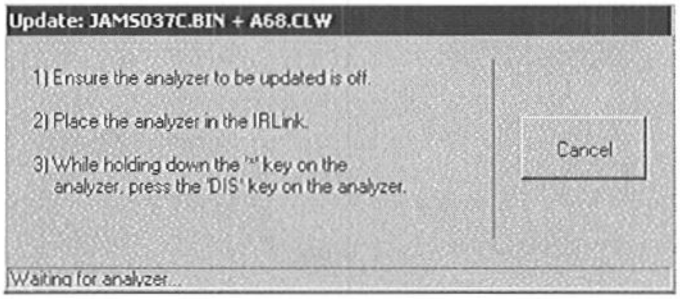
1) If an analyzer is already in the Downloader remove it.

2) Ensure the analyzer to be updated is off.

3) Place the analyzer in the Downloader.

Waiting for analyzer...

For the i-STAT Portable Clinical Analyzer:



Update: JAMS037C.BIN + A68.CLW

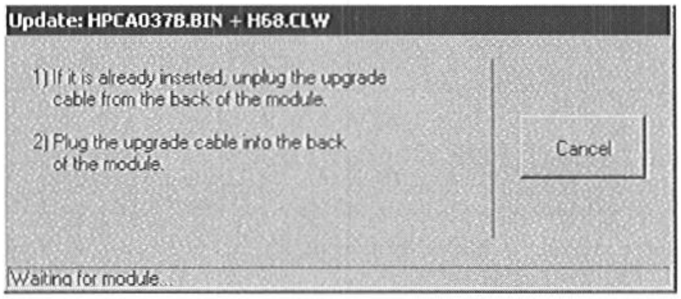
1) Ensure the analyzer to be updated is off.

2) Place the analyzer in the IRLink.

3) While holding down the '*' key on the analyzer, press the 'DIS' key on the analyzer.

Waiting for analyzer...

For the Blood Analysis Module:



Update: HPCA037B.BIN + H68.CLW

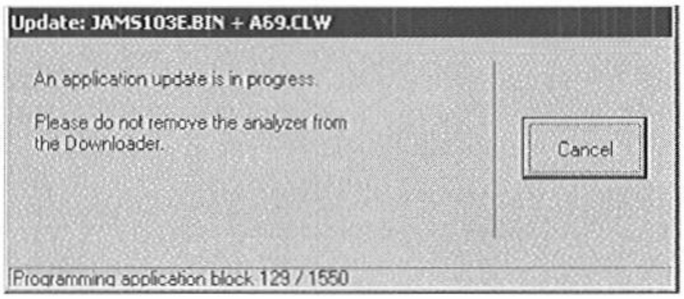
1) If it is already inserted, unplug the upgrade cable from the back of the module.

2) Plug the upgrade cable into the back of the module.

Waiting for module...

12 During the update the following screens will be displayed.

For the i-STAT 1 Analyzer:



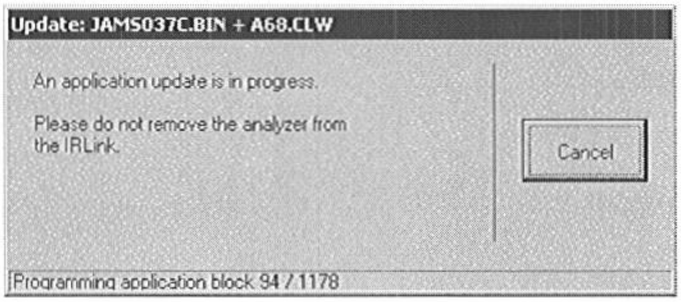
Update: JAMS103E.BIN + A69.CLW

An application update is in progress.

Please do not remove the analyzer from the Downloader.

Programming application block 129 / 1550

For the i-STAT Portable Clinical Analyzer:



Update: JAMS037C.BIN + A68.CLW

An application update is in progress.

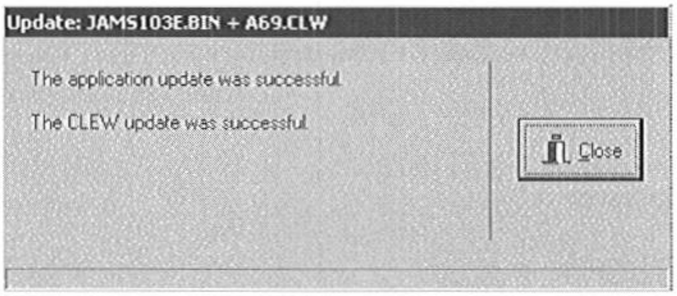
Please do not remove the analyzer from the IRLink.

Programming application block 94 / 1178

For the Blood Analysis Module:

> An application update is in progress.
>
> Please do not unplug the cable from the module.

Do not move an analyzer or unplug a Blood Analysis Module until the following screen is displayed:



Update: JAMS103E.BIN + A69.CLW

The application update was successful.

The CLEW update was successful.

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13 Click on Close. The screen in step 7 will be displayed. Make another set of selections if necessary or click on Exit to end the JammLite program.

Verifying the Update

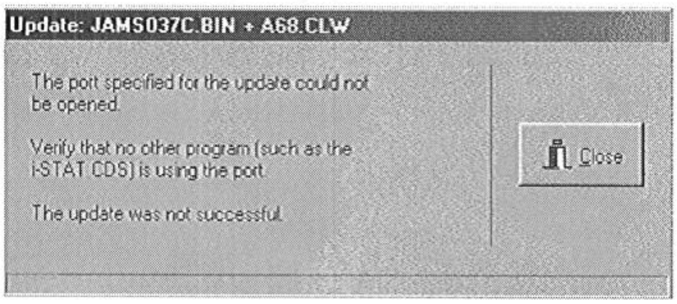
14 Run an external Electronic Simulator on updated analyzers and check the Analyzer Status page for the new Application software and/or CLEW.

Restarting the Central Data Station

15 When all analyzers have been updated, re-start the Central Data Station software, update the Customization Profile(s) with the new CLEW and enable Customization if desired.

COM port to be used for the update is not listed in the Port List. Only those ports not currently in use are listed. Exit the JammLite program and ensure that there are no other programs running which may be using the port (such as the Central Data Station). Restart the JammLite program to determine if the port is now listed.

If an error is encountered during the update, an error screen will be displayed.



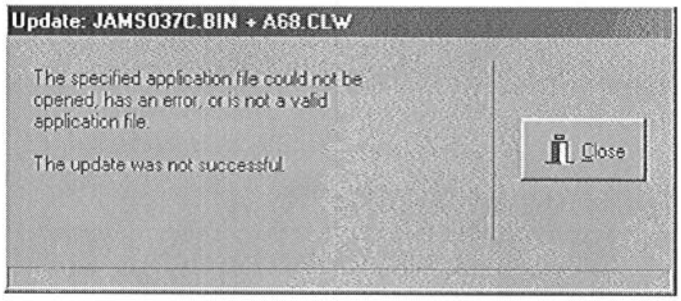
Update: JAMS037C.BIN + A68.CLW

The port specified for the update could not be opened.

Verify that no other program (such as the i-STAT CDS) is using the port.

The update was not successful.

JammLite must be the only program attempting to use the selected port. If this message is displayed, ensure that no other programs are using the port and that the correct port was selected.

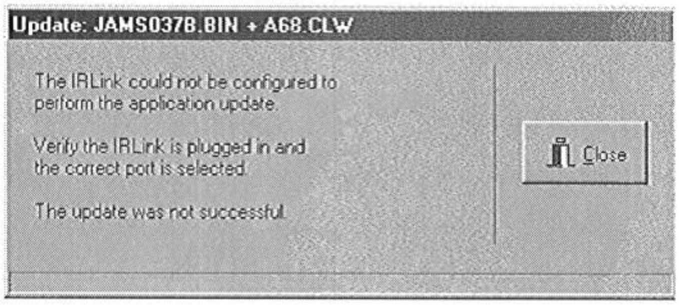


Update: JAMS037C.BIN + A68.CLW

The specified application file could not be opened, has an error, or is not a valid application file.

The update was not successful.

If this message is displayed, ensure that all other programs are closed and that the proper application was selected before re-attempting the update.



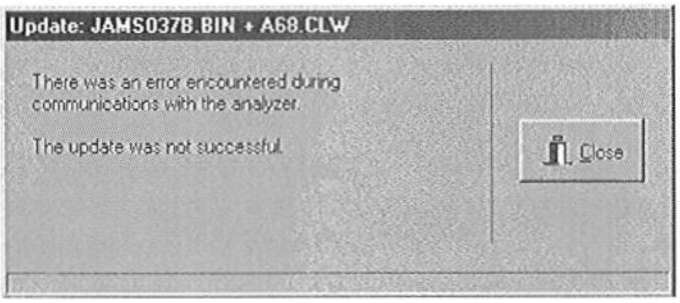
Update: JAMS037B.BIN + A68.CLW

The IRLink could not be configured to perform the application update.

Verify the IRLink is plugged in and the correct port is selected.

The update was not successful.

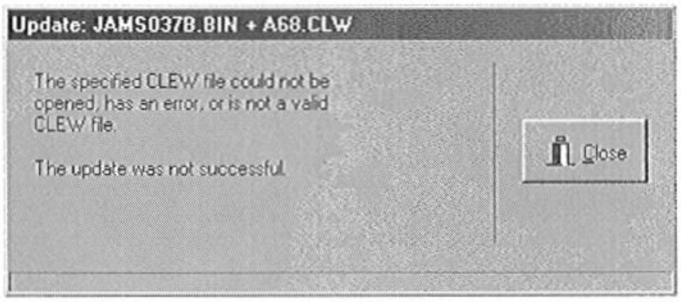
The JammLite program could not configure the IR Link. Verify that the IR Link is connected to the COM port, that the LED on the IR Link is red and the proper port is selected.


Update: JAMS037B.BIN + A68.CLW

There was an error encountered during communications with the analyzer.

The update was not successful.

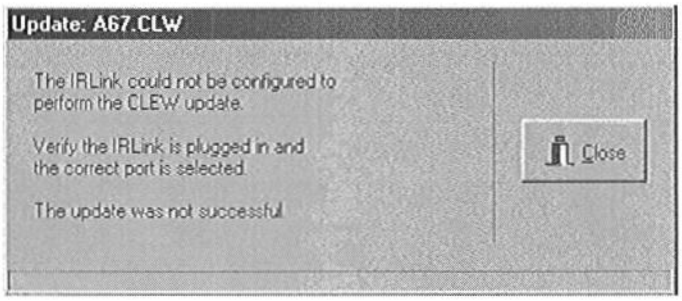
There was a problem sending the update information to the instrument. Ensure the instrument is located properly in the IR Link or Downloader, and that it is not removed before the update is completed.


Update: JAMS037B.BIN + A68.CLW

The specified CLEW file could not be opened, has an error, or is not a valid CLEW file.

The update was not successful.

Ensure that all other programs are closed and that the correct CLEW is selected before re-attempting the update.

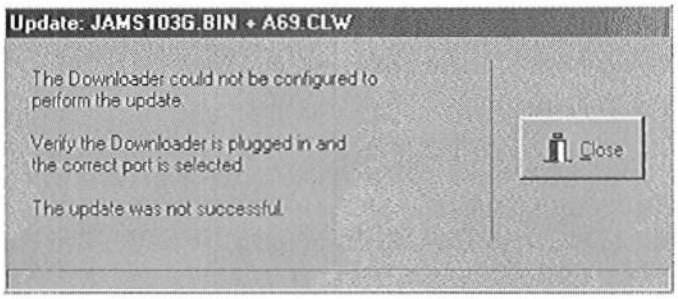

Update: A67.CLW

The IRLink could not be configured to perform the CLEW update.

Verify the IRLink is plugged in and the correct port is selected.

The update was not successful.

The JammLite program could not configure the IR Link. Verify that the IR Link is connected to the COM port, the LED on the IR Link is red, and the proper port is selected.

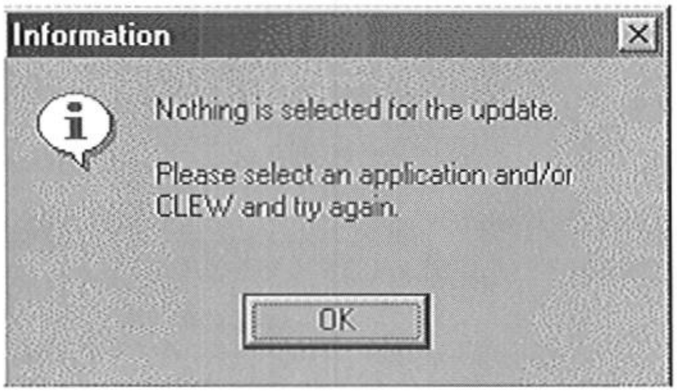

Update: JAMS103G.BIN + A69.CLW

The Downloader could not be configured to perform the update.

Verify the Downloader is plugged in and the correct port is selected.

The update was not successful.

The JammLite program could not configure the Downloader. Verify that the Downloader is connected to the COM port, the Downloader is powered, and that the proper port is selected.


Information

Nothing is selected for the update.

Please select an application and/or CLEW and try again.

Either an Application or a CLEW (or both) must be selected prior to clinking on the Update button.

Quality Check Code 13 - Invalid Expired CLEW after on-line customization is restored

If this quality check code occurs after successfully downloading new software and restoring on-line customization, the CLEW has not been updated to the new version in the Customization Profile.

Analyzer-to-Analyzer Software Updates

i-STAT 1 Analyzer

Step	Action
1	Any updated analyzer can be used as the sending analyzer. Select the Utility option under the Administration Menu on the sending analyzer. The Utility menu can be password protected. Enter the password or press the Enter key if no password has been specified. From the Utility Menu select **1-Send Software.** Select **1 – JAMS and CLEW** or **2-CLEW** as required for the update. The message "Waiting to Send" will be displayed.
2	Ensure that the receiving analyzer is off.
3	Place the sending and receiving analyzers facing each other on a flat surface about 30cm (1 foot) apart and align their IR windows. Move one analyzer toward the other until the message "Sending…" is displayed on the sending analyzer and a scrolling banner appears on the receiving analyzer.
4	Do not move the analyzers until the "Sending…" message is removed from the sending analyzer's display. The sending analyzer will return to the Send Software option and will display the result of the last software update as "Successful" or "Unsuccessful."
5	Select the Analyzer Status option under the Administration menu on the receiving analyzer and check that the new JAMS and/or CLEW are listed.

i-STAT Portable Clinical Analyzer

Step	Action
1	Any updated analyzer can be used as the Sending Analyzer. Run the external Electronic Simulator on the Sending Analyzer.
2	Transmit all data from the analyzer being updated (the Receiving Analyzer) to the Central Data Station. Data stored in the handheld analyzer will be lost after an application software update.
3	With the Simulator test results showing on the display of the Sending Analyzer, press and hold the DIS key and press the soft key for MENU. This displays the Utility Menu.
4	In the Utility Menu, select 3 - Send Software. The display will show the JAMS version and the CLEW in this analyzer. Verify that these are the appropriate versions. The analyzer screen will also say "Waiting to send".
5	Set both analyzers on a flat surface and align the Infrared Light-Emitting Diode (IR LED) windows so they directly face each other. (Refer to the analyzer picture on page 2-2 of the i-STAT System Manual for the location of the IR LED.)
6	On the Receiving Analyzer, make sure the display is off. Press and hold the * key and press the DIS key. The Sending Analyzer will begin sending software to the Receiving Analyzer. The display on the Sending Analyzer will change from "Waiting to send" to "Sending...", and a countdown bar will be displayed. Do not move the analyzers while the software is being sent.
7	When the display of the Sending Analyzer changes back to the Electronic Simulator result, the sending of software is complete. Do not press the DIS key on the Receiving Analyzer. Run the Electronic Simulator on the Receiving Analyzer.
8	To update software in another analyzer, repeat these instructions from Step 2.

i-STAT is a registered trademark of i-STAT Corporation.
Windows is a registered trademark of Microsoft Corporation.

i-STAT Calibration Verification Set
LOT Lot No: L1 B1109, L2 B1102, L3 B1094, L4 B1108, L5 B1101
Exp. Date: 31 OCT 2002

CLEW std: A76*

37°

CG8+, EG7+, EG6+, CG4+, G3+ & Crea Lot No: K, M, P, R or T (00xxx,01xxx,02xxx)

		1	2	3	4	5
Na	mmol/L mEq/L	104.3 100.9-107.7	122.0 118.6-125.4	136.0 132.1-139.9	161.0 156.6-165.4	179.0 173.8-184.2
K	mmol/L mEq/L	2.05 1.78-2.31	2.85 2.58-3.11	3.72 3.43-4.01	6.37 5.97-6.76	7.95 7.45-8.44
pH		6.828 6.779-6.877	7.181 7.132-7.230	7.461 7.412-7.510	7.704 7.655-7.753	8.136 8.087-8.185
***P*CO$_2$**	mmHg	94.68 85.40-103.96	66.83 60.28-73.38	27.94 22.55-33.33	20.03 14.89-25.17	15.60 10.70-20.50
	kPa	12.621 11.384-13.857	8.908 8.036-9.781	3.724 3.006-4.443	2.670 1.984-3.356	2.079 1.426-2.733
***P*O2**	mmHg	61.5 48.5-74.5	77.0 64.0-89.9	109.0 94.9-123.2	144.0 125.3-162.7	411.2 359.4-463.1
	kPa	8.20 6.47-9.93	10.26 8.53-11.99	14.54 12.65-16.42	19.20 16.71-21.68	54.82 47.91-61.73
***i*Ca**	mmol/L	2.197 2.067-2.327	1.48 1.388-1.572	1.233 1.156-1.310	0.798 0.733-0.863	0.334 0.277-0.391
	mg/dL	8.79 8.27-9.31	5.92 5.55-6.29	4.93 4.63-5.24	3.19 2.93-3.45	1.34 1.11-1.56
	mEq/L	4.39 4.13-4.65	2.96 2.78-3.14	2.47 2.31-2.62	1.60 1.47-1.73	0.67 0.55-0.78
Glucose	mg/dL	27.8 18.7-37.0	39.8 33.0-46.6	121.5 109.0-133.9	286.6 257.3-315.9	608.4 539.3-677.4
	g/L	0.278 0.187-0.370	0.398 0.330-0.466	1.215 1.090-1.339	2.866 2.573-3.159	6.084 5.393-6.774
	mmol/L	1.54 1.04-2.05	2.21 1.83-2.59	6.74 6.05-7.43	15.91 14.28-17.53	33.77 29.93-37.60
Creatinine	mg/dL	17.10 14.04-20.16	5.50 4.81-6.19	2.55 2.19-2.91	1.05 0.69-1.41	0.90 0.54-1.26
	umol/L	1511.6 1241.0-1782.3	486.2 425.3-547.1	225.2 193.6-256.9	92.8 61.2-124.5	79.3 47.6-111.0
Lactate	mmol/L	17.34 14.79-19.89	7.79 6.93-8.65	2.059 1.65-2.47	0.803 0.39-1.21	0.413 0.00-0.82
	mg/dL	156.3 133.3-179.2	70.2 62.5-77.9	18.55 14.9-22.2	7.24 3.6-10.9	3.72 0.0-7.4
	g/L	1.563 1.333-1.792	0.702 0.625-0.779	0.1855 0.149-0.222	0.0724 0.036-0.109	0.0372 0.000-0.074

*** or equivalent: C76, H76, J76**

See System Manual for instructions/ Anleitungen stehen in der Gebrauchsanweisung des Geraetes/ Pour plus d'informations,se reporter au Manuel Systeme/ Para las instrucciones de uso, consultar el Manual del Sistema/ Leggere le instruzioni nel manuale del sistema/Raadpleeg de systeamhandleidingvoor aanwijzingen/ Se instruktionerna i systemhandleboken.

i-STAT Corporation
East Windsor, NJ 08520
Made in USA.

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i-STAT Calibration Verification Set
LOT Lot No: L1 B1109, L2 B1102, L3 B1094, L4 B1108, L5 B1101
Exp. Date: 31 OCT 2002

CLEW std: A76*

EC8+, EC6+, 6+, EC4+, E3+ & G Lot No: A, B, C, D or E (00xxx, 01xxx,02xxx)

		1	2	3	4	5
Na	mmol/L mEq/L	103.5 100.1-106.9	122.5 119.1-125.8	135.0 131.1-138.9	160.6 156.2-165.0	178.2 173.0-183.4
K	mmol/L mEq/L	2.07 1.81-2.33	2.85 2.59-3.11	3.71 3.42-4.00	6.30 5.91-6.69	7.85 7.35-8.35
Cl	mmol/L mEq/L	63.3 59.3-67.3	75.5 71.2-79.8	90.4 85.9-94.9	116.4 110.4-122.4	128.5 121.0-136.0
pH		6.820 6.771-6.869	7.182 7.133-7.231	7.459 7.410-7.508	7.684 7.635-7.733	8.069 8.020-8.118
***P*CO$_2$**	mmHg	97.18 87.66-106.70	65.89 59.43-72.35	26.56 21.17-31.95	19.38 14.24-24.52	14.63 9.73-19.53
	kPa	12.954 11.685-14.223	8.783 7.923-9.644	3.540 2.822-4.259	2.583 1.898-3.269	1.950 1.297-2.603
***i*Ca**	mmol/L	2.292 2.162-2.422	1.568 1.470-1.666	1.314 1.232-1.396	0.859 0.794-0.924	0.363 0.306-0.420
	mg/dL	9.17 8.65-9.69	6.27 5.88-6.66	5.26 4.93-5.58	3.44 3.18-3.70	1.45 1.22-1.68
	mEq/L	4.58 4.32-4.84	3.14 2.94-3.33	2.63 2.46-2.79	1.72 1.59-1.85	0.73 0.61-0.84
Glucose	mg/dL	27.8 18.7-37.0	39.8 33.0-46.6	121.5 109.0-133.9	286.6 257.3-315.9	608.4 539.3-677.4
	g/L	0.278 0.187-0.370	0.398 0.330-0.466	1.215 1.090-1.339	2.866 2.573-3.159	6.084 5.393-6.774
	mmol/L	1.54 1.04-2.05	2.21 1.83-2.59	6.74 6.05-7.43	15.91 14.28-17.53	33.77 29.93-37.60
BUN	mg/dL	139.9 122.2-157.5	54.4 48.0-60.8	10.8 8.2-13.4	5.6 3.5-7.7	2.1 0.0-4.2
Urea	mmol/L	49.94 43.64-56.23	19.42 17.12-21.71	3.86 2.92-4.79	2.00 1.25-2.75	0.76 0.01-1.51
	mg/dL	299.3 261.6-337.1	116.4 102.6-130.2	23.1 17.5-28.7	12.0 7.5-16.5	4.6 0.1-9.1
	g/L	2.993 2.616-3.371	1.164 1.026-1.302	0.231 0.175-0.287	0.120 0.075-0.165	0.046 0.001-0.091

*** or equivalent: C76, H76, J76**

i-STAT Calibration Verification Level 5B Control
LOT Lot No: B0314
Exp. Date: 31 May 2002

CLEW std: A76*

37°

CG8+, EG7+, EG6+, CG4+, G3+ & Crea Lot No: K, M, P, R or T (00xxx,01xxx,02xxx)

Na	mmol/L	179.2
	mEq/L	174.0-184.4
K	mmol/L	8.04
	mEq/L	7.54-8.54
pH		8.140
		8.091-8.189
***P*CO$_2$**	mmHg	15.54
		10.64-20.44
	kPa	2.071
		1.418-2.725
***P*O2**	mmHg	403.9
		352.1-455.7
	kPa	53.84
		46.93-60.75
***i*Ca**	mmol/L	0.360
		0.303-0.417
	mg/dL	1.44
		1.21-1.67
	mEq/L	0.72
		0.61-0.83
Glucose	mg/dL	631.6
		559.8-703.3
	g/L	6.316
		5.598-7.033
	mmol/L	35.05
		31.07-39.04
Creatinine	mg/dL	0.82
		0.46-1.17
	umol/L	72.2
		40.6-103.9
Lactate	mmol/L	0.437
		0.03-0.85
	mg/dL	3.94
		0.3-7.6
	g/L	0.0394
		0.003-0.076

*** or equivalent: C76, H76, J76**

See System Manual for instructions/ Anleitungen stehen in der Gebrauchsanweisung des Geraetes/ Pour plus d'informations,se reporter au Manuel Systeme/ Para las instrucciones de uso, consultar el Manual del Sistema/ Leggere le instruzioni nel manuale del sistema/Raadpleeg de systeamhandleidingvoor aanwijzingen/ Se instruktionerna i systemhandleboken.

i-STAT Corporation
East Windsor, NJ 08520
Made in USA.

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i-STAT Calibration Verification Level 5B Control
LOT Lot No: B0314
Exp. Date: 31 May 2002

CLEW std: A76*

EC8+, EC6+, 6+, EC4+, E3+ & G Lot No: A, B, C, D or E (00xxx, 01xxx,02xxx)

Na	mmol/L	179.1
	mEq/L	173.9-184.3
K	mmol/L	7.94
	mEq/L	7.44-8.44
Cl	mmol/L	129.3
	mEq/L	121.8-136.8
pH		8.088
		8.039-8.137
***P*CO$_2$**	mmHg	15.15
		10.25-20.05
	kPa	2.019
		1.366-2.673
***i*Ca**	mmol/L	0.381
		0.324-0.438
	mg/dL	1.52
		1.30-1.75
	mEq/L	0.76
		0.65-0.88
Glucose	mg/dL	631.6
		559.8-703.3
	g/L	6.316
		5.598-7.033
	mmol/L	35.05
		31.07-39.04
BUN	mg/dL	2.2
		0.1-4.3
Urea	mmol/L	0.77
		0.02-1.52
	mg/dL	4.6
		0.1-9.1
	g/L	0.046
		0.001-0.091

*** or equivalent: C76, H76, J76**

i-STAT Calibration Verification Level 5B Control
LOT Lot No.: B0136
Exp. Date: 30 Nov. 2001

CLEW std: A76*

37°

CG8+, EG7+, EG6+, CG4+, G3+ & Crea Lot No: K, M, P, R or T (00xxx,01xxx,02xxx)

Na	mmol/L	176.7
	mEq/L	171.5-181.9
K	mmol/L	8.17
	mEq/L	7.67-8.67
pH		8.161 8.112-8.210
***P*CO$_2$**	mmHg	15.08 10.18-19.98
	kPa	2.010 1.357-2.663
***P*O2**	mmHg	391.7 339.9-443.5
	kPa	52.21 45.30-59.12
***i*Ca**	mmol/L	0.372 0.315-0.429
	mg/dL	1.49 1.26-1.72
	mEq/L	0.74 0.63-0.86
Glucose	mg/dL	631.1 559.4-702.7
	g/L	6.311 5.594-7.027
	mmol/L	35.03 31.05-39.01
Creatinine	mg/dL	0.89 0.53-1.24
	umol/L	78.3 46.7-110.0
Lactate	mmol/L	0.404 0.00-0.81
	mg/dL	3.64 0.0-7.3
	g/L	0.0364 0.000-0.073

*** or equivalent: C76, H76, J76**

See System Manual for instructions/ Anleitungen stehen in der Gebrauchsanweisung des Geraetes/ Pour plus d'informations,se reporter au Manuel Systeme/ Para las instrucciones de uso, consultar el Manual del Sistema/ Leggere le instruzioni nel manuale del sistema/Raadpleeg de systeamhandleidingvoor aanwijzingen/ Se instruktionerna i systemhandleboken.

42

i-STAT Corporation
East Windsor, NJ 08520
Made in USA.

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i-STAT Calibration Verification Level 5B Control
LOT Lot No.: B0136
Exp. Date: 30 Nov. 2001

CLEW std: A76*

EC8+, EC6+, 6+, EC4+, E3+ & G Lot No: A, B, C, D or E (00xxx, 01xxx,02xxx)

Na	mmol/L	176.3
	mEq/L	171.1-181.5
K	mmol/L	8.00
	mEq/L	7.50-8.50
Cl	mmol/L	129.1
	mEq/L	121.6-136.6
pH		8.096 8.047-8.145
***P*CO$_2$**	mmHg	14.53 9.63-19.43
	kPa	1.937 1.284-2.590
***i*Ca**	mmol/L	0.395 0.338-0.452
	mg/dL	1.58 1.35-1.81
	mEq/L	0.79 0.68-0.90
Glucose	mg/dL	631.1 559.4-702.7
	g/L	6.311 5.594-7.027
	mmol/L	35.03 31.05-39.01
BUN	mg/dL	2.2 0.1-4.3
Urea	mmol/L	0.79 0.04-1.54
	mg/dL	4.7 0.2-9.2
	g/L	0.047 0.002-0.092

*** or equivalent: C76, H76, J76**

i-STAT Calibration Verification Level 5B Control
LOT Lot No: B0206
Exp. Date: 31 Jan. 2002

CLEW std: A76*

37°

CG8+, EG7+, EG6+, CG4+, G3+ & Crea Lot No: K, M, P, R or T (00xxx,01xxx,02xxx)

Na	mmol/L	177.6
	mEq/L	172.4-182.8
K	mmol/L	8.04
	mEq/L	7.54-8.54
pH		8.154 8.105-8.203
***P*CO$_2$**	mmHg	15.48 10.58-20.38
	kPa	2.063 1.410-2.717
***P*O2**	mmHg	400.0 348.2-451.8
	kPa	53.32 46.41-60.23
***i*Ca**	mmol/L	0.384 0.327-0.441
	mg/dL	1.54 1.31-1.76
	mEq/L	0.77 0.65-0.88
Glucose	mg/dL	635.7 563.5-707.8
	g/L	6.357 5.635-7.078
	mmol/L	35.28 31.28-39.29
Creatinine	mg/dL	0.94 0.58-1.29
	umol/L	82.7 51.1-114.4
Lactate	mmol/L	0.429 0.02-0.84
	mg/dL	3.87 0.2-7.5
	g/L	0.0387 0.002-0.075

*** or equivalent: C76, H76, J76**

See System Manual for instructions/ Anleitungen stehen in der Gebrauchsanweisung des Geraetes/ Pour plus d'informations,se reporter au Manuel Systeme/ Para las instrucciones de uso, consultar el Manual del Sistema/ Leggere le instruzioni nel manuale del sistema/Raadpleeg de systeamhandleidingvoor aanwijzingen/ Se instruktionerna i systemhandleboken.

i-STAT Corporation
East Windsor, NJ 08520
Made in USA.

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i-STAT Calibration Verification Level 5B Control
LOT Lot No: B0206
Exp. Date: 31 Jan. 2002

CLEW std: A76*

EC8+, EC6+, 6+, EC4+, E3+ & G Lot No: A, B, C, D or E (00xxx, 01xxx,02xxx)

Na	mmol/L	177.5
	mEq/L	172.3-182.7
K	mmol/L	8.02
	mEq/L	7.52-8.52
Cl	mmol/L	130.4
	mEq/L	122.9-137.9
pH		8.090 8.041-8.139
***P*CO$_2$**	mmHg	14.49 9.59-19.39
	kPa	1.932 1.278-2.585
***i*Ca**	mmol/L	0.407 0.350-0.464
	mg/dL	1.63 1.40-1.86
	mEq/L	0.81 0.70-0.93
Glucose	mg/dL	635.7 563.5-707.8
	g/L	6.357 5.635-7.078
	mmol/L	35.28 31.28-39.29
BUN	mg/dL	2.4 0.3-4.5
Urea	mmol/L	0.84 0.09-1.59
	mg/dL	5.1 0.6-9.5
	g/L	0.051 0.006-0.095

*** or equivalent: C76, H76, J76**

i-STAT Level 1 Control
LOT Lot No: B1102
Exp. Date: 31 OCT 2002

CLEW std: A76*

37°

CG8+, EG7+, EG6+, CG4+, G3+ & Crea Lot No: K, M, P, R or T (00xxx,01xxx,02xxx)

		Mean	Range
Na	mmol/L, mEq/L	122	118-126
K	mmol/L, mEq/L	2.8	2.4-3.2
*i*Ca	mmol/L	1.48	1.37-1.59
	mg/dL	5.9	5.5-6.4
	mEq/L	3.0	2.8-3.1
pH		7.181	7.131-7.231
$P\mathrm{CO}_2$	mm Hg	66.8	58.8-74.8
	kPa	8.91	7.84-9.97
$P\mathrm{O}_2$	mm Hg	77	62-92
	kPa	10.3	8.3-12.3
Glucose	mg/dL	40	31-49
	g/L	0.40	0.31-0.49
	mmol/L	2.2	1.8-2.6
Creatinine	mg/dL	5.5	4.7-6.3
	umol/L	486	415-557
Lactate	mmol/L	7.79	6.87-8.71
	mg/dL	70.2	61.9-78.5
	g/L	0.702	0.619-0.785

EC8+, EC6+, 6+, EC4+, E3+ & G Lot No: A, B, C, D or E (00xxx, 01xxx,02xxx)

		Mean	Range
Na	mmol/L, mEq/L	122	118-126
K	mmol/L, mEq/L	2.9	2.5-3.3
Cl	mmol/L, mEq/L	76	71-81
*i*Ca	mmol/L	1.54	1.43-1.65
	mg/dL	6.2	5.7-6.6
	mEq/L	3.1	2.9-3.2
pH		7.182	7.132-7.232
$P\mathrm{CO}_2$	mm Hg	65.9	57.9-73.9
	kPa	8.78	7.72-9.85
Glucose	mg/dL	40	31-49
	g/L	0.40	0.31-0.49
	mmol/L	2.2	1.8-2.6
BUN	mg/dL	54	47-61
Urea	mmol/L	19.4	16.9-21.9
	mg/dL	116	101-131
	g/L	1.16	1.01-1.31

* or equivalent: C76, H76, J76

See System Manual for instructions/ Anleitungen stehen in der Gebrauchsanweisung des Geraetes/ Pour plus d'informations, se reporter au Manuel Systeme/ Para las instrucciones de uso, consultar el Manual del Sistema/ Leggere le instruzioni nel manuale del sistema/ Raadpleeg de systeamhandleidingvoor aanwijzingen/ Se instruktionerna i systemhandleboken.

i-STAT Corporation
East Windsor, NJ 08520
Made in USA.

014575-01
714575-01 A
09/17/01

i-STAT Level 2 Control
LOT Lot No: B1094
Exp. Date: 31 OCT 2002

CLEW std: A76*

37°

CG8+, EG7+, EG6+, CG4+, G3+ & Crea Lot No: K, M, P, R or T (00xxx,01xxx,02xxx)

		Mean	**Range**
Na	mmol/L, mEq/L	136	132-140
K	mmol/L, mEq/L	3.7	3.3-4.1
*i*Ca	mmol/L	1.23	1.15-1.31
	mg/dL	4.9	4.6-5.3
	mEq/L	2.5	2.3-2.6
pH		7.461	7.411-7.511
PCO_2	mm Hg	27.9	20.9-34.9
	kPa	3.72	2.79-4.66
PO_2	mm Hg	109	94-124
	kPa	14.5	12.5-16.5
Glucose	mg/dL	121	107-135
	g/L	1.21	1.07-1.35
	mmol/L	6.7	6.0-7.5
Creatinine	mg/dL	2.5	2.1-2.9
	umol/L	225	190-261
Lactate	mmol/L	2.06	1.56-2.56
	mg/dL	18.6	14.0-23.1
	g/L	0.186	0.140-0.231

EC8+, EC6+, 6+, EC4+, E3+ & G Lot No: A, B, C, D or E (00xxx, 01xxx,02xxx)

		Mean	**Range**
Na	mmol/L, mEq/L	135	131-139
K	mmol/L, mEq/L	3.7	3.3-4.1
Cl	mmol/L, mEq/L	90	85-95
*i*Ca	mmol/L	1.31	1.23-1.39
	mg/dL	5.3	4.9-5.6
	mEq/L	2.6	2.5-2.8
pH		7.459	7.409-7.509
PCO_2	mm Hg	26.6	19.6-33.6
	kPa	3.54	2.61-4.47
Glucose	mg/dL	121	107-135
	g/L	1.21	1.07-1.35
	mmol/L	6.7	6.0-7.5
BUN	mg/dL	11	8-14
Urea	mmol/L	3.9	2.8-4.9
	mg/dL	23	17-30
	g/L	0.23	0.17-0.30

*** or equivalent: C76, H76, J76**

See System Manual for instructions/ Anleitungen stehen in der Gebrauchsanweisung des Geraetes/ Pour plus d'informations, se reporter au Manuel Systeme/ Para las instrucciones de uso, consultar el Manual del Sistema/ Leggere le instruzioni nel manuale del sistema/ Raadpleeg de systeamhandleidingvoor aanwijzingen/ Se instruktionerna i systemhandleboken.

i-STAT Corporation
East Windsor, NJ 08520
Made in USA.

014576-01
714576-01 A
09/17/01

i-STAT Level 2 Control
LOT Lot No: B1019
⌛ Exp. Date: 31 JUL 2002

CLEW std: A76*

37°

CG8+, EG7+, EG6+, CG4+, G3+ & Crea Lot No: K, M, P, R or T (00xxx,01xxx,02xxx)

		Mean	Range
Na	mmol/L, mEq/L	136	132-140
K	mmol/L, mEq/L	3.7	3.3-4.1
*i*Ca	mmol/L	1.22	1.14-1.30
	mg/dL	4.9	4.6-5.2
	mEq/L	2.4	2.3-2.6
pH		7.468	7.418-7.518
PCO_2	mm Hg	27.3	20.3-34.3
	kPa	3.63	2.70-4.57
PO_2	mm Hg	108	93-123
	kPa	14.5	12.5-16.5
Glucose	mg/dL	122	108-136
	g/L	1.22	1.08-1.36
	mmol/L	6.8	6.0-7.6
Creatinine	mg/dL	2.6	2.2-3.0
	umol/L	230	194-265
Lactate	mmol/L	2.09	1.59-2.59
	mg/dL	18.8	14.3-23.3
	g/L	0.188	0.143-0.233

EC8+, EC6+, 6+, EC4+, E3+ & G Lot No: A, B, C, D or E (00xxx, 01xxx,02xxx)

		Mean	Range
Na	mmol/L, mEq/L	136	132-140
K	mmol/L, mEq/L	3.7	3.3-4.1
Cl	mmol/L, mEq/L	91	86-96
*i*Ca	mmol/L	1.31	1.23-1.39
	mg/dL	5.3	4.9-5.6
	mEq/L	2.6	2.5-2.8
pH		7.469	7.419-7.519
PCO_2	mm Hg	26.7	19.7-33.7
	kPa	3.56	2.63-4.49
Glucose	mg/dL	122	108-136
	g/L	1.22	1.08-1.36
	mmol/L	6.8	6.0-7.6
BUN	mg/dL	11	8-14
Urea	mmol/L	3.8	2.7-4.9
	mg/dL	23	16-29
	g/L	0.23	0.16-0.29

* or equivalent: C76, H76, J76

See System Manual for instructions/ Anleitungen stehen in der Gebrauchsanweisung des Geraetes/ Pour plus d'informations, se reporter au Manuel Systeme/ Para las instrucciones de uso, consultar el Manual del Sistema/ Leggere le instruzioni nel manuale del sistema/ Raadpleeg de systeamhandleidingvoor aanwijzingen/ Se instruktionerna i systemhandleboken.

i-STAT Corporation
East Windsor, NJ 08520
Made in USA.

014577-01
714577-01 A
09/17/01

i-STAT Level 3 Control
LOT Lot No: B1108
Exp. Date: 31 OCT 2002

CLEW std: A76*

37°

CG8+, EG7+, EG6+, CG4+, G3+ & Crea Lot No: K, M, P, R or T (00xxx,01xxx,02xxx)

		Mean	**Range**
Na	mmol/L, mEq/L	161	156-166
K	mmol/L, mEq/L	6.4	5.9-6.9
*i*Ca	mmol/L	0.80	0.72-0.88
	mg/dL	3.2	2.9-3.5
	mEq/L	1.6	1.4-1.8
pH		7.704	7.654-7.754
$\boldsymbol{P}CO_2$	mm Hg	20.0	14.0-26.0
	kPa	2.67	1.87-3.47
$\boldsymbol{P}O_2$	mm Hg	144	126-162
	kPa	19.2	16.8-21.6
Glucose	mg/dL	287	245-329
	g/L	2.87	2.45-3.29
	mmol/L	15.9	13.6-18.2
Creatinine	mg/dL	1.1	0.7-1.5
	umol/L	93	57-128
Lactate	mmol/L	0.80	0.30-1.30
	mg/dL	7.2	2.7-11.7
	g/L	0.072	0.027-0.117

EC8+, EC6+, 6+, EC4+, E3+ & G Lot No: A, B, C, D or E (00xxx, 01xxx,02xxx)

		Mean	**Range**
Na	mmol/L, mEq/L	161	156-166
K	mmol/L, mEq/L	6.3	5.8-6.8
Cl	mmol/L, mEq/L	116	110-122
*i*Ca	mmol/L	0.86	0.78-0.94
	mg/dL	3.4	3.1-3.8
	mEq/L	1.7	1.6-1.9
pH		7.684	7.634-7.734
$\boldsymbol{P}CO_2$	mm Hg	19.4	13.4-25.4
	kPa	2.58	1.78-3.38
Glucose	mg/dL	287	245-329
	g/L	2.87	2.45-3.29
	mmol/L	15.9	13.6-18.2
BUN	mg/dL	6	4-8
Urea	mmol/L	2.0	1.3-2.7
	mg/dL	12	8-16
	g/L	0.12	0.08-0.16

*** or equivalent: C76, H76, J76**

See System Manual for instructions/ Anleitungen stehen in der Gebrauchsanweisung des Geraetes/ Pour plus d'informations, se reporter au Manuel Systeme/ Para las instrucciones de uso, consultar el Manual del Sistema/ Leggere le instruzioni nel manuale del sistema/ Raadpleeg de systeamhandleidingvoor aanwijzingen/ Se instruktionerna i systemhandleboken.

i-STAT Corporation
East Windsor, NJ 08520
Made in USA.

014578-01
714578-01 B
10/04/01

i-STAT ACT Level 1 Control
LOT Lot No. B01150
Exp. Date: 31 May 02

CLEW std: A76*

37°

Celite ACT Lot No: K,M,P,R or T (00xxx,01xxx,02xxx)

		Mean	Range
ACT (WBT)	sec	175	123-228

*** or equivalent: C76, H76, J76**

See System Manual for instructions/ Anleitungen stehen in der Gebrauchsanweisung des Geraetes/ Pour plus d'informations, se reporter au Manuel Systeme/ Para las instrucciones de uso, consultar el Manual del Sistema/ Leggere le instruzioni nel manuale del sistema/ Raadpleeg de systeamhandleidingvoor aanwijzingen/ Se instruktionerna i systemhandleboken.

i-STAT Corporation
East Windsor, NJ 08520
Made in USA.

014579-01
714579-01 A
09/17/01

i-STAT ACT Level 2 Control

LOT Lot No. B01124
⌛ Exp. Date: 31 May 02

CLEW std: A76*

37°

Celite ACT Lot No: K,M,P,R or T (00xxx,01xxx,02xxx)

		Mean	Range
ACT (WBT)	sec	613	429-797

*** or equivalent: C76, H76, J76**

See System Manual for instructions/ Anleitungen stehen in der Gebrauchsanweisung des Geraetes/ Pour plus d'informations, se reporter au Manuel Systeme/ Para las instrucciones de uso, consultar el Manual del Sistema/ Leggere le instruzioni nel manuale del sistema/ Raadpleeg de systeamhandleidingvoor aanwijzingen/ Se instruktionerna i systemhandleboken.

i-STAT Corporation
East Windsor, NJ 08520
Made in USA.

014580-01
714580-01 A
09/17/01

Nov 01

i-STAT

TECHNICAL BULLETIN

INSTRUCTIONS FOR UPDATING ANALYZER SOFTWARE

This Technical Bulletin details the steps required to change the application software and/or CLEW in any i-STAT Portable Clinical Analyzer with thermal control 37 and/or Agilent Technologies (formerly Hewlett Packard) M1022A Blood Analysis Module for Viridia Patient Monitors (collectively referred to as "Analyzer"). Please follow these directions carefully. If you have any questions or require assistance with this procedure, please call Technical Service.

Setting up the Computer

If using an i-STAT Central Data Station

If using an i-STAT Central Data Station (CDS) to update the Analyzers, follow the steps below for setting up the computer:

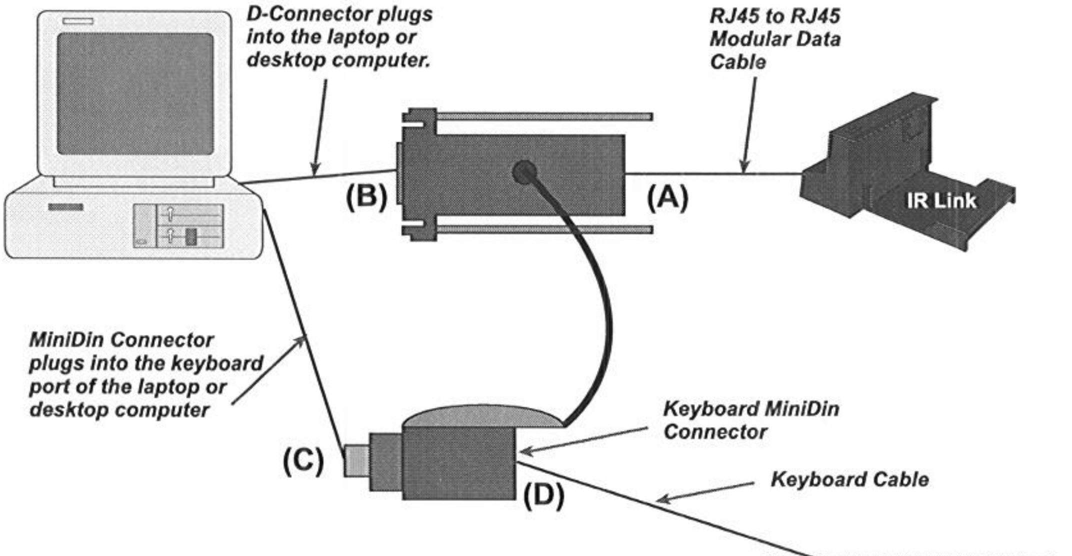
Step	Action
1	If updating handheld analyzers, transmit all data from the handhelds to the CDS. Data stored in a handheld analyzer will be lost after an application software update.
⚠ **Attention:**	If the Analyzer Customization Profile Utility is enabled in your Central Data Station, disable it prior to starting this process. The profile can be saved for restoration. **For additional information on doing this, refer to the i-STAT Technical Bulletin, "Instructions for the Analyzer Customization Profile Utility".** Once Analyzers are updated, the function to restore the profile can be used to re-enable on-line customization, if desired. **However, be sure to first select the new CLEW in the profile.**
2	Connect a Modular Data Cable to the COM5 port on the back of the CDS. If your Central Data Station has one quad card (four ports for data cables), COM 5 is the innermost port closet to the fan. If your CDS has two quad cards, COM 5 is the innermost port on the bottom row of ports. If updating handheld analyzers, connect an IR Link to the opposite end of the cable.
3	Click on *Exit* to close the Central Data Station application.
4	Exit the Windows application following the instructions below for your platform: Windows 3.1 platform: Click on FILE and then EXIT in the Program Manager. Windows 95/98 platform: Click the Start button, select Shut Down..., then select Restart in DOS mode. Windows NT platform: Click the Start button, select Programs, then select Command Prompt. With Windows 95/98 and NT platforms, you will be at the C:\WINDOWS prompt on exiting. Return to the root directory by typing cd\ and pressing the **Enter** key.
5	Place the diskette labeled "Software for Analyzers" into the A: drive.

6	At the C:\> prompt, type **A:TRANSFER** and press the ENTER key. Wait for the DOS prompt C:\BINS> to appear. Ignore any "File Not Found" or "Directory Already Exists" messages that may appear.
7	At the C:\BINS> prompt, type **JAMMIT** and press the ENTER key. The i-STAT Configuration Utility will appear.
8	Proceed with the section of this document titled "Downloading to an Analyzer".

If you are using any other IBM PC compatible/ Point-of-Care Central Workstation

If using any other IBM PC compatible to update the analyzers, follow the steps below for setting up the computer:

Step	Action
1	If updating handheld analyzers, transmit all data from the handhelds to the CDS. Data stored in a handheld analyzer will be lost after an application software update.
2	Connect a Modular Data Cable to one of the 9-pin connector COM ports on the PC using the power adapter according to instructions supplied with it or the picture below. If updating handheld analyzers, connect an IR Link to the opposite end of the cable.
3	Exit all applications. You must be at the MS DOS prompt. (See Step 4 under *"If Using an i-STAT Central Data Station."*)
4	Place the diskette labeled "Software for Analyzers" into the A: drive.
5	At the C:\> prompt, type **A:TRANSFER** and press the ENTER key. Wait for the DOS prompt C:\BINS> to appear. Ignore any "File Not Found" or "Directory Already Exists" messages that may appear.


D-Connector plugs into the laptop or desktop computer.
RJ45 to RJ45 Modular Data Cable
(B)
(A)
IR Link
MiniDin Connector plugs into the keyboard port of the laptop or desktop computer
Keyboard MiniDin Connector
(C)
(D)
Keyboard Cable

6	At the C:\BINS> prompt, type **JAMMIT** and press the ENTER key. The i-STAT Configuration Utility will appear.
7	Using the UP/DOWN arrow keys, highlight **Utility Setup** and press the ENTER key.
8	Using the UP/DOWN arrow keys, highlight **COM Port**. Using the RIGHT/LEFT arrow keys, select 1 or 2, depending on where the 9-pin connector is connected.
9	Using the UP/DOWN arrow keys, highlight **Return to Main Menu** and press the ENTER key.
10	Proceed with the section of this document titled "Downloading to an Analyzer".

Downloading Software to an Analyzer

Downloading to a handheld analyzer

Follow the steps below to download software to a handheld analyzer:

Step	Action
1	Highlight **Software** and press the ENTER key. The window **Select Files to Download** appears. The menu items **Application** and **CLEW** will automatically be set to the newest version.
2	Confirm the setting for **Application** and **CLEW** against the Product Update accompanying the diskette. If, under specific instruction from i-STAT, different versions are to be downloaded, highlight the menu item you are to change using the UP/DOWN arrow keys and use the LEFT/RIGHT arrow keys to set the proper version. **Note:** If the software upgrade is only a **CLEW**, select "None" for application.
3	Highlight **Download Selection** and press the ENTER key.
4	Follow the instructions on the computer screen. **Do not move the analyzer while download is in progress. Do not press the DIS key. When download is complete, run the Electronic Simulator in the Analyzer.** **Note:** On the handheld status page, the Application name is displayed on the line labeled **Ver:** and the CLEW is displayed on the line labeled **CLEW**.
5	After the update of all handheld analyzers is complete, the function to restore the Customization Profile can be used to re-enable on-line customization if desired. **Be sure to select the new CLEW in the profile first. Failure to do this will result in Quality Check Code 13.**

Downloading to a Blood Analysis Module

Follow the steps below to download software to a Blood Analysis Module:

Step	Action
1	Highlight **Utility Setup** and press ENTER key. The window Utility Setup appears.
2	Using the UP/DOWN arrow keys, highlight **Analyzer**. Using the RIGHT/LEFT arrow keys, select **HP Blood Analysis Module**.
3	Highlight **Return to Main Menu** and press the ENTER key.
4	Highlight **Software** and press the ENTER key. The window **Select Files to Download** appears. The menu items **Application** and **CLEW** will automatically be set to the newest version.

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5 Confirm the setting for **Application** and **CLEW** against the Product Update accompanying the diskette. If, under specific instruction from i-STAT, different versions are to be downloaded, highlight the menu item you are to change using the UP/DOWN arrow keys and use the LEFT/RIGHT arrow keys to set the proper version.

Note: If the software upgrade is only a **CLEW**, select "None" for application.

6 Highlight **Download Selection** and press the ENTER key.

7 Follow the instructions on the computer screen. **Do not unplug the module while the download is in progress.**

Note: When the module is returned to a monitor, the CLEW can be viewed in the Blood Analysis Setup screen.

8 After the update of all modules is complete, the function to restore the Customization Profile can be used to re-enable on-line customization if desired. Be sure to select the new CLEW in the profile first.

Sending Software from handheld to handheld

To send software from one handheld analyzer to another, follow the instructions below:

Step	Action
1	Any updated analyzer can be used as the **Sending Analyzer**. Run the external Electronic Simulator on the Sending Analyzer.
2	Transmit all data from the analyzer being updated (the **Receiving Analyzer**) to the Central Data Station. Data stored in the handheld analyzer will be lost after an application software update.
3	With the Simulator test results showing on the display of the Sending Analyzer, press and hold the DIS key and press the soft key for MENU. This displays the Utility Menu.
4	In the Utility Menu, select 3 - **Send Software**. The display will show the JAMS version and the CLEW in this analyzer. Verify that these are the appropriate versions. The analyzer screen will also say "Waiting to send".
5	Set both analyzers on a flat surface and align the Infrared Light-Emitting Diode (IR LED) windows so they directly face each other. (Refer to the analyzer picture on page 2-2 of the i-STAT System Manual for the location of the IR LED.)
6	On the Receiving Analyzer, make sure the display is off. Press and hold the * key and press the **DIS** key. The Sending analyzer will begin sending software to the Receiving Analyzer. The display on the Sending Analyzer will change from "Waiting to send" to "Sending...", and a countdown bar will be displayed. **Do not move the analyzers while the software is being sent.**
7	When the display of the Sending Analyzer changes back to the Electronic Simulator result, the sending of software is complete. **Do not press the DIS key. Run the Electronic Simulator on the Receiving Analyzer.**
8	To update software in another analyzer, repeat these instructions from Step 2.

Troubleshooting

Error message relating to the IR Link	If you are using any other IBM PC compatible computer, another application may be monopolizing the COM port. Close all other open applications. Ensure the utility is set to use the proper COM port in the Utility Setup option from the main menu. If the setting is proper, quit the Utility, turn off the computer, unplug and replug the IR Link, restart the computer, and try the download again.
UPDATE .cfg not found	Ensure you run A:TRANSFER from an i-STAT software diskette. Ensure you run **JAMMIT** from C:\BINS> .
Block count stops incrementing	If the block count on the status line of the computer screen stops incrementing for more than 10 seconds during a download, press the **Esc** key to abort the download. If updating an handheld analyzer, take it out of the IR Link, remove and replace the batteries to reset. If updating a Blood Analysis Module, unplug the cable and plug it in again. This can happen if you try to run **JAMMIT** under Microsoft Windows (Windows 3.1 or 95/98 platform). You must exit Windows and run the program in the DOS mode. Try the download again.
Nothing happens OR Handheld displays results or error message when *DIS is pressed as prompted	Remove and replace the batteries to reset the handheld. Ensure the handheld display is off. Place the handheld back in the cradle, ensure it is properly seated. Press and hold the * key for 2 seconds, then press the **DIS** key while keeping the * key pressed.
LEDs on the module are OFF	Possibly the cable or the COM port is defective. Try another cable and/or configure another port to "HP Blood Analysis Module" and try again.
Quality Check Code 13 - Invalid Expired CLEW after on-line customization is restored	If this quality check code occurs after successfully downloading new software and restoring on-line customization, the CLEW has not been updated to the new version in the Customization Profile. Refer to i-STAT Technical Bulletin "Instructions for the Analyzer Customization Profile Utility.

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i-STAT

TECHICAL BULLETIN

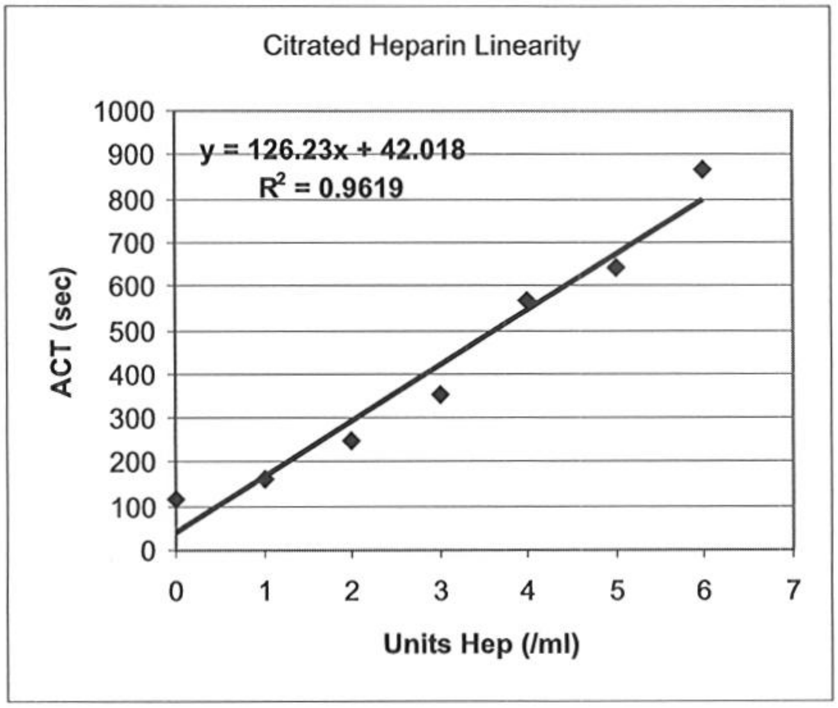
i-STAT Celite ACT Heparin Linearity Procedure

INTRODUCTION

The i-STAT® Celite® ACT is intended for *in vitro* diagnostic use. This test can be performed at the bedside using venous or arterial whole blood. The i-STAT Celite ACT is commonly used for heparin anticoagulation monitoring for adults during cardiopulmonary bypass (CPB) surgery and percutaneous transluminal coronary angioplasty (PTCA). The i-STAT Celite ACT can be performed using the i-STAT Portable Clinical Analyzer or i-STAT 1 Analyzer. The reportable range of the i-STAT Celite ACT test is from 50-1000 seconds.

The i-STAT Celite ACT test has demonstrated linearity between 0.0 and 6.0 units of heparin in blood samples from normal, healthy volunteers.

An *in vitro* heparin sensitivity curve was generated by adding increasing amounts of heparin to aliquots of normal donor blood (See graph below which serves as an example only. Each patient demonstrates a unique dose-response curve.)



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If an attempt is being made to reproduce and demonstrate the manufacturer's claims as they relate to the linearity and sensitivity of the Celite ACT test, the following procedure may be used. An *in vitro* laboratory assay of heparin sensitivity is a universally accepted method of evaluating the ACT assay performance. An acceptable degree of linearity in a heparin dose-response sensitivity curve is a universally accepted indication of ACT performance validation. Heparin sensitivity curves are generated using either citrated or fresh donor whole blood. Incremental concentrations of heparin are added to aliquots of the blood specimen. The i-STAT Celite ACT test is performed using these specimens.

Linearity Procedure for using CITRATED WHOLE BLOOD

Materials

i-STAT Celite ACT cartridges (14)

Plastic test tubes, no additives (7)

Large collection tube for heparin dilution, 10 mL minimum, no additives (1)

Large plastic collection tube for blood pooling, 10 mL minimum, no additives (1)

1,000 units/mL USP Heparin (beef lung or porcine)

Isotonic Saline (9.0 mL)

0.025M Calcium Chloride

Precision pipettes (1,000 µL)

3.2 or 3.8% Sodium Citrate evacuated blood collection tubes (blue top) for 9mL collection (i.e., 2 x 4.5mL tubes).

Procedure

Note: *Although clinical testing utilizes fresh whole blood exclusively, for the purposes of the linearity assessment citrated whole blood can be substituted.*

Note: *When using a citrated whole blood source clotting times may be slightly higher than when using fresh whole blood.*

1. Obtain 14 i-STAT Celite ACT cartridges and two i-STAT Analyzers.
2. Using a standard pharmaceutical heparin preparation (either beef or porcine derived material from any manufacturer), dilute the heparin using saline to a concentration of 100 units/mL of total volume. This can be accomplished by adding 9.0 mL of saline to 1.0 mL of standard USP heparin supplied at 1,000 units/mL.
3. Label seven (7) plastic test tubes in the following manner: "A", "B", "C", "D", "E", "F", and "G". Dispense the following quantities of the diluted heparin into the respective test tubes. The final concentration of heparin in the plastic test tubes after the addition of blood and calcium can be found in the table below.

Tube	Amount of Heparin (µL)	Final Heparin Concentration (units/mL)	Total Heparin Units
A	0	0	0
B	10	1.0	1.0
C	20	2.0	2.0
D	30	3.0	3.0
E	40	4.0	4.0
F	50	5.0	5.0
G	60	6.0	6.0

4. Obtain at least two 4.5 cc blue top (3.8% or 3.2% sodium citrate) tubes. Gently mix the tubes end to end 10 times. (Note: a total of 9.0 mL of citrated whole blood is needed and pooled in the larger collection tube)

5. Accurately dispense 0.70 mL of the citrated blood sample to each one of the seven test tubes prepared in step 3. ("A", "B", "C", "D", "E", "F" and "G"). These are the tubes to which the heparin has previously been added. After adding the blood sample, gently mix the tubes by inversion.

6. Starting with test tube "A" add 0.30 mL of 0.025M Calcium Chloride to the tube. Mix thoroughly. (Do not add Calcium Chloride to the tube until ready to run the cartridge(s) for that heparin level.)

7. Immediately, use a plastic transfer pipet or a tuberculin syringe to dispense the mixture into the sample well of of 2 Celite ACT cartridges. Begin the test.

8. Record the Celite ACT results.

9. Repeat steps 6 through 9 for all tubes "B", "C", "D", "E", "F" and "G". **Note:** Before testing tubes B – G, mix gently by inversion.

10. Record the clotting times and graph the results using, "Avg. Celite ACT seconds" on the y-axis and "Heparin Concentration" (units/mL) on the x-axis.

Result Interpretation

Inspection of the dose-response curve will identify a linear sensitivity response. Linearity is defined statistically by the correlation coefficient (r value) of the assay, which should be = 0.88.

Notes:

Due to the variability of heparin sensitivity, high levels may yield out of range high results. An intermediate amount of heparin can be used to perform linearity (e.g. 35 µL). The actual values obtained for a given heparin level will vary among donors. The heparin type (beef or porcine), manufacturer source and lot number of the heparin preparation will also affect results. The maximum concentration of heparin at which a donor's blood will clot is dependent upon physiologic characteristics of the donor. Extremely elevated clotting times can be excluded from the analysis.

Linearity Procedure for using FRESH WHOLE BLOOD

Materials

i-STAT Celite ACT cartridges (14)

Plastic test tubes, no additives (7)

Large plastic collection tube for heparin dilution, 20 mL, no additives (1)

1,000 units/mL USP Heparin (beef lung or porcine)

Isotonic Saline (9.0 mL)

Precision pipettes (1,000 uL)

Procedure

1. Obtain 14 i-STAT Celite ACT cartridges and at least two i-STAT Analyzers.
2. Using a standard pharmaceutical heparin preparation (either beef or porcine derived material from any manufacturer), dilute the heparin using saline to a concentration of 100 units/mL of total volume. This can be accomplished by adding 9.0 mL of saline to 1.0 mL of standard USP heparin supplied at 1,000 units/mL.
3. Label seven (7) plastic test tubes in the following manner: "A", "B", "C", "D" "E", "F" and "G".
4. Dispense the following quantities of the diluted heparin into the respective test tubes. The final concentration of heparin in the plastic test tubes after the addition of 1.0 mL fresh whole blood can be found in the table below.

Tube	Amount of Heparin (μL)	Final Heparin Concentration (units/mL)	Total Heparin Units
A	0	0	0
B	10	1.0	1.0
C	20	2.0	2.0
D	30	3.0	3.0
E	40	4.0	4.0
F	50	5.0	5.0
G	60	6.0	6.0

5. Using a butterfly needle and a 10 cc syringe, obtain 9.0 cc of fresh whole blood from a normal healthy donor who is not currently taking medications.
6. Accurately dispense 1.0 mL of the fresh whole blood sample to each of the seven (previously prepared) plastic test tubes A to G and gently mix by inversion.
7. Immediately using plastic transfer pipet or a tuberculin syringe withdraw about 0.3 mL of the unheparinized blood from tube A and dispense into 2 Celite ACT cartridges. Begin the test.
8. Record the Celite ACT results.
9. Repeat steps 7-9 for blood samples "B", "C", "D" "E", "F" and "G".

   Note: Before testing tubes B – G, mix gently by inversion.
10. Record the clotting times and graph the results, using "Avg. ACT seconds" on the y-axis and "Heparin Concentration" (units/mL) on the x-axis.

Result Interpretation

Inspection of the dose-response curve will identify a linear sensitivity response. Linearity is defined statistically by the correlation coefficient (r value) of the assay, which should be ≥ 0.88.

Notes: Due to variability of heparin sensitivity, high levels may yield out of range high results. An intermediate amount of heparin can be used to perform linearity (e.g. 35 μL). The actual values obtained will vary among donors. The heparin type (beef or porcine), manufacturer source and lot number of the heparin preparation will also affect results. The maximum concentration of heparin at which donor blood will clot is dependent upon physiologic characteristics of the donor. Extremely elevated clotting times can be excluded from the analysis.

HEPARIN LINEARITY DATA COLLECTION SHEET

Operator Name	

Sample Type	**Citrated Whole Blood** ☐	**Fresh Whole Blood** ☐

Date	**Facility Name**	
	Analyzer Serial Number	
	i-STAT Celite ACT Lot #	

Hep Conc (u/ml)	**Clotting Time (sec)**		
	ACT 1 (sec)	**ACT 2 (sec)**	**Average (sec)**
0			
1			
2			
3			
4			
5			
6			

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Celite is a registered trademark of Celite Corporation, Santa Barbara,CA, for its diatomaceous earth products.

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i-STAT

TECHNICAL BULLETIN

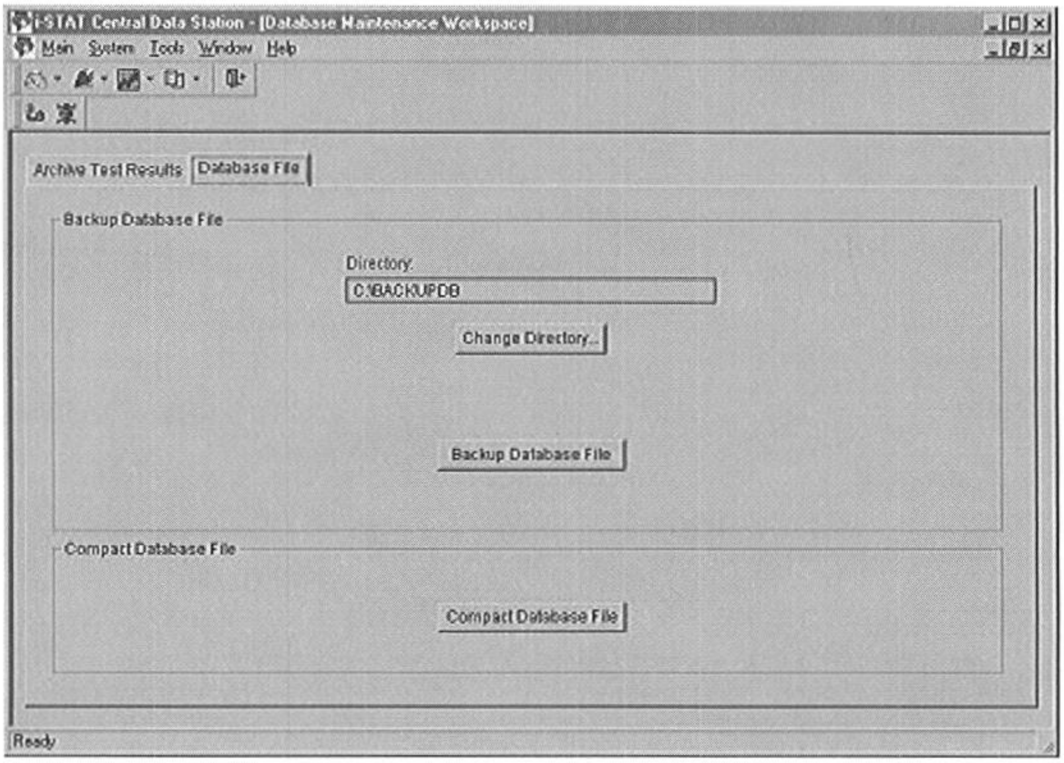
October 2001 Update to i-STAT System Manual: Central Data Station Version 5

Introduction

The October 2001 software update for the Central Data Station Version 5 (CDS5) includes a new Database Compaction function and also, some new customizable items that are applicable only to the i-STAT1 Analyzer. See Customization Workspace in the System Manual for information on customizing the analyzer through the Central Data Station.

Database Maintenance Workspace

A Database Compaction function has been added to the Database Workspace. When the backup and delete or delete only functions are used, data is removed but the space the data took up in the file is not. The compaction function creates a new copy of the database with the excess space removed creating a smaller and, therefore, more responsive database.


i-STAT Central Data Station - [Database Maintenance Workspace]
Main System Tools Window Help
Archive Test Results
Database File
Backup Database File
Change Directory...
Backup Database File
Compact Database File
Compact Database File
Ready

Directory: C:\BACKUPDB

Customization Workspace: Not Applicable to the Portable Clinical Analyzer

Password: Password protection for the Set Clock function can be enabled or disabled. The default setting is Enabled.

Check Digit: A check digit algorithm can be applied to manually entered patient and/or operator IDs.

Barcodes: Two barcode types have been added for scanning patient and operator IDs: EAN-8 and EAN-128.

Print Reference Ranges: Reference ranges can be printed with results.

Electronic Simulator Schedule: A new schedule option for the Internal and External Simulator runs the Internal Simulator or prompts for the External Simulator after an indicated number of patient tests.

Chart Page: The order of the items listed on the Chart page can be changed and any item can be set as a mandatory entry.

Operator Workspace: Not Applicable to the Portable Clinical Analyzer

Operator List Import: A new function in the Operator Workspace on the CDS5 allows an operator list to be imported from a text file.

i-STAT

TECHNICAL BULLETIN

Proficiency Testing and Comparison of Methods on the i-STAT® System

This Technical Bulletin covers two closely related CLIA regulations: *Subpart H—Participation in Proficiency Testing* and *Subpart P—Quality Assurance, paragraph 493.1709: Comparison of Test Results*. Together, proficiency testing and comparison of test results should ensure that the accuracy and reliability of test results are established and maintained. All laboratories should now be in compliance with these regulations.

Proficiency Testing

The regulation requires a laboratory to enroll in a proficiency testing (PT) program approved by the Health Care Financing Administration (HCFA) for its primary test system or that system used at its primary site. The laboratory must participate successfully as defined by the criteria defined in *Subpart I—Proficiency Testing Programs.*

A primary testing system is defined as the only method or the primary method for performing and reporting tests under a CLIA certificate. The i-STAT System is a primary testing system when:

- A hospital has separate CLIA certificates for the main laboratory and point-of-care testing;
- A hospital owns a clinic, same-day-surgery, kidney dialysis unit, etc., which requires a separate CLIA certificate;
- The i-STAT System is the hospital's primary laboratory testing system; or
- The i-STAT System is the main testing system in a physician's office, skilled nursing facility, unaffiliated patient transport service, home healthcare agency, etc.

Proficiency testing programs must provide three separate shipments during the year that include five challenges for each analyte or test. Laboratories must test these samples exactly as they would patient samples and return the results within a specified time to the provider for grading.

PT Programs for the i-STAT System

There are several PT program providers such as the College of American Pathologists (CAP), the American Association of Bioanalysts, and the American Proficiency Institute. Several states have HCFA approved PT programs as well. Each of these providers has several PT-surveys to choose from. In general, aqueous-based PT surveys are recommended. Certain PT survey samples are not compatible with the sensors or may contain interfering substances that could affect results.

- Fluorocarbon samples for blood gases and fixed-cell samples for hematocrit are not compatible with the sensors.
- Protein based or serum samples may contain high levels of ammonium ions that can suppress the glucose sensor results.

The CAP's AQ2 Survey provides both aqueous and protein based samples and is the most comprehensive of the PT surveys including all analytes. CAP's AQ survey does not contain BUN/Urea. The Q or Comprehensive Chemistry Survey can be used for BUN/Urea but is not the optimal choice for other analytes.

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CAP Surveys Program

Instrument Codes:

The CAP has set aside multiple "instrument codes" for the i-STAT System. ***The proper code, however, is determined not by the i-STAT instrument but rather by the specific i-STAT cartridge you use to analyze the sample.***

> **NOTE***:* In general, test results from cartridges which are thermally controlled (look for the 37° symbol) will differ from results obtained from cartridges which are not thermally controlled WHEN-USING-AN-AQUEOUS-SAMPLE, such as the CAP PT sample. All test results **WILL** be consistent regardless of cartridge type when using a whole blood sample.

The following four (4) codes cover all situations. Specify one of the following instrument codes when submitting PT results to the CAP. ***Please note, code descriptions have changed.***

Cartridge Type **37° cartridges G3+, EG6+, and EG7+** **Non 37° cartridges G, E3+, EC4+, 6+, EC6+, and EC8+**	**Instrument Code**	**Cap Instrument Master List**
i-STAT 37° cartridges	**G64**	i-STAT 37° cartridges
i-STAT non-37° cartridges All A, B and C Lots	**M04**	i-STAT non-37°, A, B or C 98XXX, 99XXX
i-STAT non-37° cartridges All K, M or P Lots	**M06**	i-STAT non-37°, K, M or P 98XXX, 99XXX

Method Principle Codes:

Sodium	208	ion selective electrode (direct)
Potassium	208	ion selective electrode (direct)
Chloride	208	ion selective electrode (direct)
Ionized calcium		use instrument code
pH		use instrument code
PCO_2		use instrument code
PO_2		use instrument code
Urea	520	ammonium ion selective electrode, urease
Glucose	106	glucose oxidase O_2 electrode
Hematocrit	i-STAT	conductivity

Comparison of Test Results

The CLIA regulations require that, twice a year, a laboratory evaluate and define the relationship between different methodologies, instruments, or testing sites. If the laboratory is not performing proficiency testing on the i-STAT System, then a comparison of test results procedure must be performed using the i-STAT System and the system on which proficiency is performed. There is no established protocol or criteria to meet the Comparison of Test Results standard. Inspectors will not expect to see the type of method comparison study that is used to establish or verify the performance characteristics of new test system. The following points should be considered when writing a procedure to comply with this standard. A split-sample procedure can be used where the same sample is divided and tested on two or more systems to compare test results.

The i-STAT System

The i-STAT System consists of any number of i-STAT Portable Clinical Analyzers and HP M1022A Blood Analysis Modules for OmniCare CMS Patient Monitors (collectively known as "Analyzer"). All Analyzers that pass the Electronic Simulator are equivalent. Therefore, PT samples san be tested on any Analyzer that has passed the Electronic Simulator.

In general, cartridges which are thermally controlled ("blood gas cartridges" with the blue 37° symbol) will produce different results in aqueous samples, such as CAP PT sample, than will cartridges which are not thermally controlled. All types will read consistently in blood samples.

Samples

Only fresh whole blood patient samples should be tested on the i-STAT System for comparison of test results. Matrix effects that can be encountered with commercially prepared samples can prevent proper evaluation of results.

Number of Samples

While PT programs must provide five challenges three times a year for each test, the number of samples to be included in the comparison of test results protocol is not prescribed by CLIA. A comparison of test results protocol should cover normal and abnormal values with a limited number of samples.

In order to obtain abnormally high and low values, it will be necessary to draw samples from patients rather than volunteers from the facility's staff. This may require prior selection of particular patients based on previous results or diagnosis as well as permission from patients, physicians, or an Internal Review Board.

Sample Handling

Proper sample handling is paramount to a successful evaluation. Sufficient blood should be drawn into a lithium heparin vacuum tube for the i-STAT and comparative chemistry test system(s) or into a blood gas syringe for the i-STAT and other blood gas testing system. An EDTA tube should be drawn for the comparative hematocrit test system(s).

Note: If more than one lithium heparin tube must be drawn, a tube-to-tube variable may be introduced.

The time interval between testing on the two (or more) test systems should be ten minutes or less. Otherwise, time induced differences in the sample may affect results. If the test systems are located at some distance from each other, arrangements should be made in advance to ensure minimum sample transport time. Samples should be tested on the i-STAT System and any other whole blood testing systems and then immediately transported to the sample processing area for centrifugation.

Note: When participating in a PT program, it is required that PT samples be tested in the same manner as patients' samples by personnel who routinely perform the testing. When designing a comparison of test results procedure, samples should be tested by the i-STAT System operators.

Schedule

While test result comparisons are required twice a year, it is not necessary to test five samples every six months. Split-sample testing can be scheduled through out the year on a documented schedule.

Evaluation of Results

Evaluation of results should be based on pre-established acceptability criteria. Acceptability criteria could be based on medically allowable differences between two systems within the facility provided that the differences determined in the initial performance verification did not exceed these values. CLIA limits for PT results could be used provided that the differences determined in the initial performance verification did not exceed these values.

Corrective Action

If a set of results falls outside the expected range, controls could be tested on the different systems to try and determine which system is not performing according to specifications. After the cause has been determined and corrected, a second sample should be tested. All results and corrective actions should be documented.

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PCO_2 and calculated values for HCO_3, TCO_2, Base Excess and Anion Gap

PCO_2 is measured by direct potentiometry. In the calculation of results for PCO_2, concentration is related to potential through the Nernst equation. Results are measured at 37°C when using cartridges that require thermal control and corrected to 37°C when using cartridges that do not require thermal control. The performance characteristics of the sensors are equivalent in all cartridge configurations.

Calculated Values

When a cartridge includes sensors for both pH and PCO_2, bicarbonate (HCO_3), total carbon dioxide (TCO_2) and base excess (BE) can be calculated.[1]

$$\log HCO_3 = pH + \log PCO_2 - 7.608$$
$$TCO_2 = HCO_3 + 0.03\ PCO_2$$

$$BE_{ecf} = HCO_3 - 24.8 + 16.2\ (pH - 7.4)$$

When a cartridge includes sensors for sodium, potassium, chloride, pH and PCO_2, anion gap can be calculated.

$$\text{Anion Gap} = (Na + K) - (Cl + HCO_3)$$

See below for information on factors affecting results. Certain substances, such as drugs, may affect analyte levels *in vivo*.[2] If results appear inconsistent with the clinical assessment, the patient sample should be retested using another cartridge.

Intended Use

The test for PCO_2, as part of the i-STAT System, is intended for use in the *in vitro* quantification of arterial, venous, or capillary whole blood.

Contents

Each i-STAT cartridge contains one reference electrode (when potentiometric sensors are included in the cartridge configuration); sensors for measurement of specific analytes and a buffered aqueous calibrant solution of known concentrations. For cartridges that contain a sensor for the measurement of PCO_2, the calibrant solution contains 30mm Hg of PCO_2.

Expected Values

Test/Abbreviation	Units	Reportable Range	Reference Range (arterial)	Reference Range (venous)
Partial Pressure Carbon Dioxide/PCO_2	mm Hg	5 – 130	35 – 45[3]	41 – 51
	kPa	0.67 – 17.330	4.67 – 6.00	5.47 – 6.80
Bicarbonate/HCO_3	mmol/L	1 – 85	22 – 26*	23 – 28*
Total Carbon Dioxide/TCO_2	mmol/L	1 – 85	23 – 27*	24 – 29*
Base Excess/BE	mmol/L	(-30) – (+30)	(-2) – (+3)[3]	(-2) – (+3)[3]
Anion Gap/AnGap	mmol/L	(-10) – (+99)	10 – 20[3]	10 – 20[3]

*Calculated from Siggaard-Andersen nomogram.

For TCO_2, values measured on serum or plasma by chemistry analyzers may be slightly lower than TCO_2 calculated from pH and PCO_2 due to loss of CO_2 during non-anaerobic handling.[5] Up to 6mmol/L CO_2 can be lost per hour by exposure of the sample to air.[6]

For the measurement of PCO_2, the i-STAT System has been calibrated to agree with standard blood gas methods performed on whole blood at 37°C.

The reference ranges programmed into the analyzer and shown above are intended to be used as guides for the interpretation of results. Since reference ranges may vary with demographic factors such as age, gender and heritage, it is recommended that reference ranges be determined for the population being tested.

Clinical Significance

PCO_2 along with pH is used to assess acid-base balance. PCO_2 (partial pressure of carbon dioxide), the respiratory component of acid-base balance, is a measure of the tension or pressure of carbon dioxide dissolved in the blood. PCO_2 represents the balance between cellular production of CO_2 and ventilatory removal of CO_2 and a change in PCO_2 indicates an alteration in this balance. Causes of primary respiratory acidosis (increase in PCO_2) are airway obstruction, sedatives and anesthetics, respiratory distress syndrome, and chronic obstructive pulmonary disease. Causes of primary respiratory alkalosis (decreased PCO_2) are hypoxia (resulting in hyperventilation) due to chronic heart failure, edema and neurologic disorders, and mechanical hyperventilation.

HCO_3 (bicarbonate), the most abundant buffer in the blood plasma, is an indicator of the buffering capacity of blood. Regulated primarily by the kidneys, HCO_3 is the metabolic component of acid-base balance. Causes of primary metabolic acidosis (decrease in HCO_3) are ketoacidosis, lactate acidosis (hypoxia), and diarrhea. Causes of primary metabolic alkalosis (increase in HCO_3) are vomiting and antacid treatment.

TCO_2 (total carbon dioxide) is either measured on plasma by automated chemistry analyzers or is calculated from pH and PCO_2 measured on whole blood gas analyzers. TCO_2 is a measure of carbon dioxide which exists in several states: CO_2 in physical solution or loosely bound to proteins, HCO_3 or CO_3 ions, and carbonic acid (H_2CO_3). Bicarbonate ions make up all but approximately 2mmol/L of the total carbon dioxide of plasma. Measurement of TCO_2 as part of an electrolyte profile is useful chiefly to evaluate HCO_3 concentration. TCO_2 and HCO_3 are useful in the assessment of acid-base imbalance (along with pH and PCO_2) and electrolyte imbalance.

Base excess of the extracellular fluid or standard base excess is defined as the concentration of titratable base minus the concentration of titratable acid when titrating the average intracellular fluid (plasma plus interstitial fluid) to an arterial plasma pH of 7.40 at PCO_2 of 40 mm Hg at 37°C. Excess concentration of base in the average ECF remains virtually constant during acute changes in the PCO_2 and reflects only nonrespiratory component of pH-disturbances.

Anion gap is reported as the difference between the commonly measured cations sodium and potassium and the commonly measured anions chloride and bicarbonate. The size of the gap reflects unmeasured cations and anions and is therefore an analytical gap. Physiologically, a deficit of anions cannot exist. While relatively nonspecific, anion gap is useful for the detection of organic acidosis due to an increase in anions that are difficult to measure. Anion gap can be used to classify metabolic acidosis into high and normal anion gap types. Anion gap may be only slightly increased in diarrhea and renal failure, but elevated (often >25) due to an increase in organic anions in lactic acidosis, ketoacidosis (alcoholic, diabetic, starvation) and uremia, an increase in inorganic anions in uremia, and an increase in anions from drugs such a salicylate and carbenicillin or toxins such as methanol and ethanol.

Performance Characteristics

The typical performance data summarized below was collected in a health care facility by health care professionals trained in the use of the i-STAT System and comparative methods.

Precision data was collected in multiple sites using the Performance Verification Guideline found in the i-STAT Implementation Guide. Similar results can be expected in future performance studies provided the same experimental design and data analysis procedures are followed. Method comparison data was collected using NCCLS guideline EP5.[7] Venous blood samples were collected in blood gas syringes. To measure TCO_2, the sample was centrifuged to obtain plasma. All samples were analyzed in duplicate on the i-STAT System and on the comparative methods within 10 minutes of each other.

Arterial blood samples were collected from hospital patients in 3cc blood gas syringes and were analyzed in duplicate on the i-STAT System and the Radiometer ABL500 within 5 minutes of each other.

Deming regression analysis[8] was performed on the first replicate of each sample. In the method comparison table, n is the number of specimens in the data set, Sxx and Syy refer to estimates of imprecision based on the duplicates of the comparative and the i-STAT methods respectively, Sy.x is the standard error of the estimate, and r is the correlation coefficient.*

Method comparisons will vary from site to site due to differences in sample handling, comparative method calibration and other site specific variables.

* The usual warning relating to the use of regression analysis is summarized here as a reminder: For any analyte, "if the data is collected over a narrow range, the estimate of the regression parameters are relatively imprecise and may be biased. Therefore, predictions made from these estimates may be invalid".[7] The correlation coefficient, r, can be used as a guide to assess the adequacy of the comparative method range in overcoming this problem. As a guide, the range of data can be considered adequate if r>0.975.

Factors Affecting Results*

Exposing the sample to air allows CO_2 to escape which causes PCO_2 to decrease and pH to increase and HCO_3 and TCO_2 to be under-estimated.

Allowing blood to stand (without exposure to air) before testing allows PCO_2 to increase and pH to decrease, which will cause HCO_3 and TCO_2 to be over-estimated, due to metabolic processes.

Interferent	Effect
Propofol (Diprivan®)	Procedures that involve sustained (>1hour) administration of propofol at rates in excess of 50 µg/kg/min (3 mg/kg/hour) may result in significant errors in i-STAT PCO_2 results. Alternately, such administration may result in the automated suppression of PCO2 and pH results ("star-outs") by the analyzer's quality system. Use an alternative method to measure PCO_2 when administering propofol at rates in excess of this level. Consider an alternative method when administering propofol at any sustained rate to patients with renal impairment. See note (1) and (3) below.
Thiopental Sodium	Sustained administration (over more than a few minutes) of thiopental sodium, either by continuous or intermittent drips, may result in plasma concentrations of thiopental sodium that yield significant errors in i-STAT PCO_2 results. Alternately, such administration may result in the automated suppression of PCO2 and pH results ("star-outs") by the analyzer's quality system. Use an alternate method to measure PCO_2 when administering thiopental sodium on a sustained basis. See note (2) and (3) below.

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*It is possible that other interfering substance may be encountered. These results are representative and your results may differ somewhat due to test-to-test variation. The degree of interference at concentrations other than those listed might not be predictable.

Notes:

1) Propofol is an intravenous sedative-hypnotic agent. Among its applications are the induction and maintenance of anesthesia and the sedation of intubated, mechanically ventilated patients. Although propofol itself does not directly interfere with the measurement of PCO_2 on the i-STAT System, decreases in PCO_2 of > 5 mmHg (0.67 kPa) have been observed on some patients due to metabolic byproducts of propofol, as a result of sustained (>1hr) administration at rates in excess of 50 µg/kg/min (3 mg/kg/hour). At doses of 50-100 µg/kg/min (3-6mg/kg/hour) some errors as large as 10 mmHg or 1.33 kPa.(below 40 mmHg or 5.33 kPa) or 25% (above 40 mmHg or 5.33 kPa) were observed. At doses significantly above 100 µg/kg/min (6 mg/kg/hour) we have observed errors as large as 40% for administration in excess of 5 hours, although more typically results were suppressed by the analyzer (***displayed). Below 50 µg/kg/min, decreases are typically less than 3 mmHg but sometimes as large as 5 mmHg (0.67 kPa). We have observed no decreases when a single dose of propofol is administered to induce anesthesia. We advise caution, however, when administering propofol to any patient with renal impairment as this may affect the clearance rate of metabolic byproducts.

2) Thiopental Sodium (*syn.* thiomebumal sodium, penthiobarbital sodium, thiopentone sodium, thionembutal, Pentothal Sodium®, Nesdonal Sodium®, Intraval Sodium®, Trapanal®, and Thiothal Sodium[9]) is an ultra-short-acting, intravenous anesthetic. It is used as an induction agent for general anesthesia, to control status epilepticus, in the treatment of intracranial hypertension, and in narcoanalysis of psychiatric disorders. Sustained administration (over more than a few minutes) of thiopental sodium may lead to >5 mmHg (0.67 kPa) decreases in PCO_2 results. Errors observed on patient samples have been as large as 20 mmHg (2.67 kPa). For single dose administration of thiopental given over a few minutes, such as in the induction of anesthesia, interference on the i-STAT PCO_2 is modest (<10% at 40 mmHg or 5.33 kPa, <15% at 70 mmHg or 9.33 kPa) approximately 15 minutes after administration of typical doses, since thiopental is rapidly absorbed from the bloodstream, falling below 10 µg/mL within 15 minutes[10]. The interference will continue to diminish as the drug continues to be absorbed.

3) As of the date of revision of this document, improvements to the PCO_2 test are under development to reduce or eliminate propofol and thiopental sodium interferences. Contact your i-STAT System technical support provider for the most current information on availability.

Precision Data (mmHg)

Aqueous Control	Mean	SD	%CV
Level 1	63.0	1.72	2.73
Level 3	19.4	0.70	3.59

Method Comparison (mmHg)

	PCO_2 IL BGE	TCO_2 IL BGE	TCO_2 Beckman CX®3	Radiometer ABL500
n	62	62	51	45
Sxx	0.69	0.40	0.55	0.549
Syy	1.24	0.84	0.55	1.059
Slope	1.003	1.136	1.155	0.958
Int't	-0.8	-4.1	-2.6	1.036
Sy.x	1.65	1.38	1.56	11.460
Xmin	30.4	19.3	18.3	
Xmax	99.0	43.9	36.1	
r	0.989	0.965	0.935	0.995

References

1. NCCLS. *Blood Gas and pH Analysis and Related Measurements; Proposed Guidelines.* NCCLS document C46-P [ISBN 1-56238-399-X]. NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA 2000.

2. D.S. Young, *Effects of Drugs on Clinical Laboratory Tests,* 3rd ed. (Washington, DC: American Association of Clinical Chemistry, 1990).

3. P.C. Painter, J.Y. Cope, J.L. Smith, *"Reference Ranges, Table 41–20" in Tietz Textbook of Clinical Chemistry—Second Edition,* C.A. Burtis and E.R. Ashwood, eds. (Philadelphia: W.B. Saunders Company, 1994).

4. E.L. Pruden, O. Siggaard-Andersen, and N.W. Tietz, *Blood Gases and pH,* in Tietz Textbook of Clinical Chemistry, Second Edition, ed. C.A. Burtis and E.R. Ashwood. (Philadelphia: W.B. Saunders Company).

5. J.P.J. Ungerer, M.J. Ungerer, and W.J.H Vermaak, Discordance Between Measured and Calculated Total Carbon Dioxide, Clinical Chemistry 36.12, 1990. 2093-2096.

6. N.W. Tietz, E.L. Pruden, O. Siggaard-Andersen, Electrolytes, in Tietz Textbook Clinical Chemistry Second Edition, ed. C.A. Burtis and E.R. Ashwood. (Philadelphia: W.B. Saunders Company 1994).

7. NCCLS. *Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline.* NCCLS document EP9-A [ISBN 1-56238-283-7]. NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA 1995.

8. P.J. Cornbleet and N. Gochman, "Incorrect Least-Squares Regression Coefficients in Method-Comparison Analysis," *Clinical Chemistry* 25:3, 432 (1979).

9. The Merck Index, Eleventh Edition, Merck & Co., Inc, NJ, 1989.

10. P.G. Burgh and D.R. Stanski, Anesthesiology, 58:146-152, 1983.

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CX®3 is a registered trademark of Beckman Instruments, Inc., Brea, CA USA.

Diprivan is a registered trademark of the AstraZeneca group of companies.

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Intraval Sodium is a registered trademark of May and Baker, Ltd., England.

Trapanal is a registered trademark of Chemische Fabrik Promonta, Germany.

June 02

DOCUMENTATION UPDATES AND SOFTWARE UPGRADE FOR THE i-STAT SYSTEM

In addition to important updates to documentation about the i-STAT® System, this package contains the necessary items to perform the required software upgrades on your i-STAT System. Items enclosed are detailed in the table below. Please follow instructions carefully. Thank you for your prompt attention in performing this upgrade.

Contact i-STAT Technical Service at 800-366-8020, option 1, if you have any questions or need further assistance.

DOCUMENTATION UPDATES

ITEM	COMMENT	SENT TO		
		all users	i-STAT 1 users only	users of CDS ver. 5
Technical Bulletin: Troubleshooting Caution	New document to update all System Manuals.	X		
Technical Bulletin: Calibration Verification for Analytes on the Portable Clinical Analyzer	New document to update i-STAT System Manual.	X		
Technical Bulletin: Proficiency Testing and External Quality Control Testing on the Portable Clinical Analyzer	New document to update i-STAT System Manual.	X		
Technical Bulletin: Proficiency Testing on the i-STAT System	Revised document to update all System Manuals.	X		
Technical Bulletin: Compensation for Extreme Altitude and Barometric Pressure on *P*O2 Results in Aqueous Material	Revised document to update i-STAT System Manual.	X		

SOFTWARE UPGRADE

DOCUMENT	COMMENT	SENT TO		
		all users	i-STAT 1 users only	users of CDS ver. 5
Product Update: JAMS043 / HPCA043 / MINT043 / MNCA043 / JAMS110 / MINT110 CDS version 4.04.1c / CDS version 5.11	Describes changes in new software.	X		
Disk: i-STAT Software for Analyzers (standard)	One disk contains all versions of STANDARD software.	X		
Disk: i-STAT Software for Analyzers (MINT)	One disk contains all versions of MINT software.	(sent only by request)		
Technical Bulletin: Updating Analyzer Software: JAMMLITE Utility, Ver. 3.0	For use in updating software using a computer with Windows 95 or higher. JAMMLITE must be used for updating i-STAT 1 Analyzers.	X		
Technical Bulletin: Instructions for Updating Software	For use in updating software from a computer with Windows 3.1.	X		
CD-ROM: Central Data Station Version 5.11	Only for CDS version 5.			X
Disk: Central Data Station Version 4.04.1c	Only for CDS version 4.	X		
Control and **Calibration Verification Value Assignment Sheets**	Upgrade support documentation.	X		
Confirmation postcard	Complete and return to i-STAT **after** upgrade has been performed.	X		

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Product
Update

SOFTWARE UPDATE

This update includes new software for the i-STAT 1 Analyzer, i-STAT Portable Clinical Analyzer, Philips Medical Systems Blood Analysis Module, Central Data Station Version 4 and Central Data Station Version 5. The appropriate materials required for your institution to perform the update are included. New values assignment sheets for current quality control and calibration verification solutions are included in this update package.

This is a mandatory update. If you have not received a disk with the correct software for your analyzers (see list below) or a CD ROM for 5.11 for your Central Data Station Version 5 or a Disk for 4.04.1c for your Central Data Station Version 4, please call to request one. In the US and Canada, call i-STAT Technical Support at 877-529-7185. Outside the US, please contact your local Abbott support representative.

ANALYZERS

The correct version of software and CLEW to install in your analyzers is dependant upon whether your institution has chosen to use standard JAMS software or MINT software. See the Cartridge and Test Information sheet for PCO_2 for the use of MINT software.

Standard Software

i-STAT Portable Clinical Analyzer: JAMS043 & CLEW A84
i-STAT Portable Clinical Analyzer – Japan: JAMS043 & CLEW C84
i-STAT 1 Analyzer: JAMS110 & CLEW A84
i-STAT 1 Analyzer – Japan: JAMS110 & CLEW A84
Philips Medical Systems Blood Analysis Module: HPCA043 CLEW H84
Philips Medical Systems Blood Analysis Module – Japan: HPCA043 CLEW J84

MINT Software

i-STAT Portable Clinical Analyzer: MINT043 & CLEW D23
i-STAT Portable Clinical Analyzer – Japan: MINT043 & CLEW E23
i-STAT 1 Analyzer: MINT110 & CLEW D23
i-STAT 1 Analyzer – Japan: MINT110 & CLEW D23
Blood Analysis Module: MNCA043 CLEW N23
Blood Analysis Module – Japan: MNCA043 CLEW V23

Expiration Date

Please note that the current software expires 12 September 2002.
Fifteen days before the software expires a message will be displayed to alert the user of the pending expiration date. If this update is not performed by 12 September 2002, the analyzer and Blood Analysis Modules will display "INVALID OR EXPIRED CLEW - SEE MANUAL" (quality check code 12).

This software expires 18 December 2002

2

CENTRAL DATA STATION

Central Data Station Version 4	If you have a CDS4, install the disk labeled 4.04.1c according to the directions on the disk label.
Central Data Station Version 5	If you are running CDS5 software on your Point of Care Central Data Station, install the CD labeled 5.11 following the directions on the label.

CHANGES

Support of manufacturing changes

Changes have been made in the Analyzer software to assure compatibility with manufacturing process changes to the cartridges. Future shipments of cartridges may require the installation of this software prior to use of the cartridges. Failure to update prior to using these cartridges will result in quality check code 69, "CARTRIDGE TYPE NOT RECOGNIZED".

This software continues to support all current unexpired cartridges.

Portable Clinical Analyzer

Two new test paths have been added to the analyzer: Proficiency Testing and Calibration Verification. For details see the Procedure section in the enclosed Technical Bulletins "Proficiency and External Quality Control Testing on the Portable Clinical Analyzer" and "Calibration Verification for Analytes on the Portable Clinical Analyzer."

The benefit of using the Proficiency Test path for these tests is that the hematocrit results reported will be standardized to K3EDTA samples regardless of how the analyzer is customized. This should create consistent results across all reporting sites.

With the addition of the Calibration Verification test path, patient and control samples tested via the standard test path will always be marked as out-of-range (< or >) when they are less than or greater than the reportable range. Using the Calibration Verification path, measured values can be reported for samples that exceed the reportable range.

Blood Analysis Module

Currently the two new test paths described above for the Portable Clinical Analyzer are not available on the Blood Analysis Module.

i-STAT1 Analyzer

The Proficiency Testing test path will now report hematocrit results that are standardized to K3EDTA samples regardless of how the analyzer is customized, which should create consistent results across all sites. See the Technical Bulletin "June 2002 Update for i-STAT1 System Manual" for other minor changes that should be noted in your system manual.

CDS 4.04.1c

Support for PT (Prothrombin Time) cartridges has been added. Updates have been incorporated to maintain compatibility with current cartridges and analyzer functionality.

CDS 5.11 Support for PT (Prothrombin Time) cartridges has been added. The HL7 interface is now active. "None" has been added to the list of interface protocols on the Interface Tab. (None can be used when there is no interface and MediSense PCx glucose test strip results from i-STAT 1 Analyzers are to be uploaded to QC Manager 2.2.) The checkbox to enable the upload of glucose test strip results to QC Manager has been moved to this Interface Tab. This checkbox was originally on the Interface Options Tab in the Interface Customization program. Updates have been incorporated to maintain compatibility with current cartridges and analyzer functionality.

STANDARDIZATION

CLEW update The i-STAT System is designed to eliminate operator influence on delivered results. Unlike other unit-use systems, the user is not required to enter lot-specific calibration information into the instrument. The micro-fabricated sensor technology produces very repeatable material from lot to lot which allows the Analyzers to use the same set of standardizing values for extended periods of time.

Nevertheless, the continuous manufacturing process improvements by i-STAT necessitate re-establishing standardization values from time to time to maintain long-term consistency. This is equivalent to adjusting calibration on a traditional analyzer. It has been our practice to accomplish this with periodic releases of software. This new CLEW re-establishes the standardization and incorporates refinements to the internal quality monitoring system.

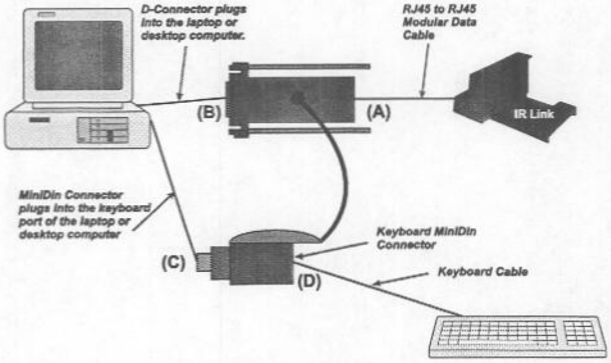
i-STAT

TECHNICAL BULLETIN

UPDATING ANALYZER SOFTWARE: JAMMLITE UTILITY

The JammLite Utility must be used to update software in the i-STAT®1 Analyzer and can be used to update the i-STAT Portable Clinical Analyzer and the Blood Analysis Module. The JammLite procedure is simple with just one screen for all analyzer types and software versions.

To use this utility, you must have a Central Data Station or a computer with Windows® 95 or higher.

	Step	Action
Save the Analyzer Data	1	Download data from the i-STAT Portable Clinical Analyzers before an application update since all data will be erased during the update procedure. Data is not erased from the i-STAT 1 Analyzer.
Shut Down All Programs	2	If the Central Data Station application is running on the computer, disable Customization and exit the CDS application. If using another computer, exit all applications.
Connect IR Link and/or Downloader	3	**IR Link connection:** • If using a Central Data Station Version 5, a Central Data Station Version 4 with digiboard, or any other computer using Windows 95 or above, connect the IR Link to a 9 pin COM port using an i-STAT Software Update Kit as illustrated below.  D-Connector plugs into the laptop or desktop computer. RJ45 to RJ45 Modular Data Cable (B) (A) IR Link MiniDin Connector plugs into the keyboard port of the laptop or desktop computer Keyboard MiniDin Connector (C) (D) Keyboard Cable • If using a Central Data Station Version 4 connect the IR Link to COM5 on the back of the CDS using a Modular Data Cable (i-STAT grey flat cable with RJ45 connectors). **Blood Analysis Module connection:** • If using a Central Data Station Version 4, connect the BAM to COM5 on the back of the CDS using a Modular Data Cable (i-STAT grey flat cable with RJ45 connectors). • If using a Central Data Station Version 5 or another computer, connect the BAM to a 9 pin COM port using the D-Connector and Mini Din Connector from an i-STAT Software Update Kit.
	Note:	Do not connect the BAM until instructed to do so by the JammLite program.

Serial Downloader connection:

- Connect a serial Downloader to a COM port using a DB9-DB9 Null Modem cable and plug the Downloader's power adapter into a wall outlet.

Network Downloader connection:

- Connect a network Downloader to the network using a network patch cable and plug the Downloader's power adapter into a wall outlet. The computer must also be connected to the network. The computer must support the TCP/IP network protocol.

Copy the Files

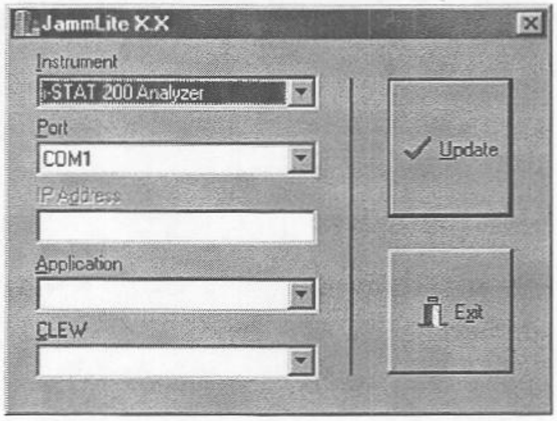
4 Access a command prompt on the computer. (Click **Start,** then **Run...**and type **command** into the box provided.)

5 Place the diskette labeled "Software for Analyzers" into the A:drive.

6 At the C:\> prompt, type **A:transfer** and press the Enter key.

Using the JammLite Utility

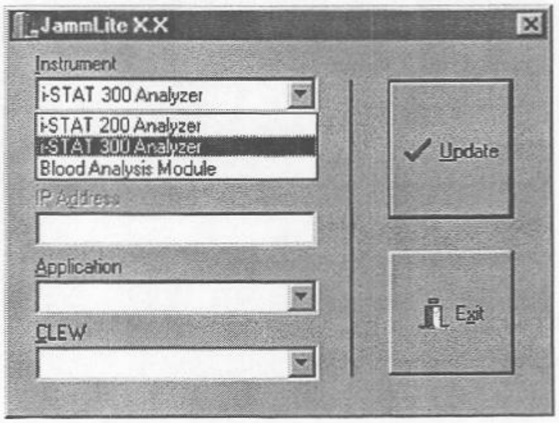
7 At the C:\>bins prompt, type **jammlite** and press the Enter key. The following screen will be displayed with the new application and CLEW.


JammLite X.X
IP Address
Application
CLEW
Update
Exit

Instrument: i-STAT 200 Analyzer
Port: COM1

X.X is the current version of JammLite software.

8 Select the appropriate instrument from the Instrument drop-down list.


JammLite X.X
i-STAT 200 Analyzer
i-STAT 300 Analyzer
Blood Analysis Module
IP Address
Application
CLEW
Update
Exit

Instrument: i-STAT 300 Analyzer

i-STAT 200 Analyzer is the Portable Clinical Analyzer and the i-STAT 300 Analyzer is the i-STAT 1 Analyzer.

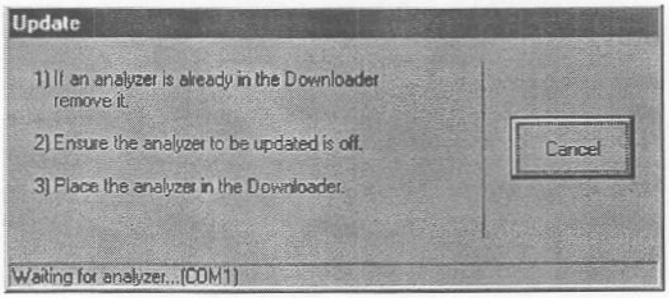
9 Select the port for the instrument being updated from the "Port" drop-down list. The JammLite program will list only available ports on the computer. For updates using a network Downloader, select TCP/IP. (The TCP/IP option is available only if i-STAT 300 is selected from the "Instrument" drop down list.) Enter the IP address of the Downloader in the "IP Address" box.

10 Select the appropriate Application and CLEW from the Application and CLEW drop-down lists. Refer to the update package for the correct Application and CLEW. If the update is for CLEW only, select None for Application. Note that there are different application versions for the i-STAT 1 Analyzer, the Portable Clinical Analyzer and the Blood Analysis Module. JammLite will display all application software and CLEW appropriate for the selected instrument.

---

11 Click on the Update button to start the update. Appropriate instructions will be displayed. Follow the directions on the screen. The selected application and CLEW will be displayed on the Update Line.

For the i-STAT 1 Analyzer:



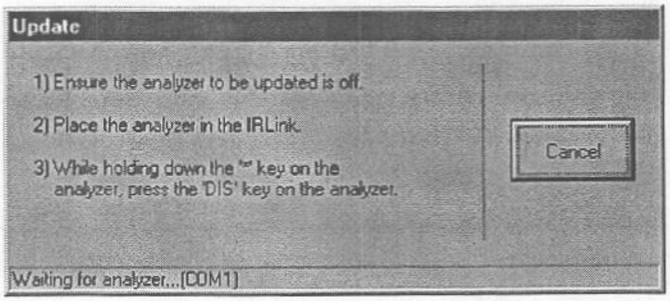
1) If an analyzer is already in the Downloader remove it.

2) Ensure the analyzer to be updated is off.

3) Place the analyzer in the Downloader.

Waiting for analyzer...(COM1)

For the i-STAT Portable Clinical Analyzer:



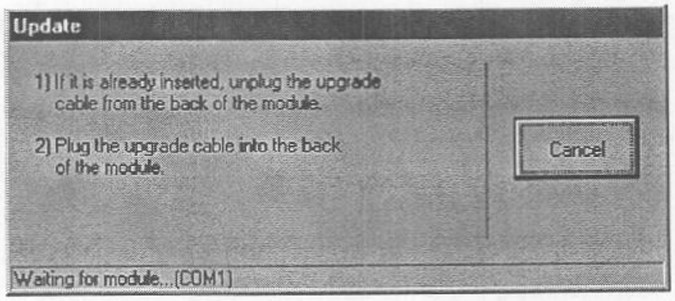
1) Ensure the analyzer to be updated is off.

2) Place the analyzer in the IRLink.

3) While holding down the '*' key on the analyzer, press the 'DIS' key on the analyzer.

Waiting for analyzer...(COM1)

For the Blood Analysis Module:



1) If it is already inserted, unplug the upgrade cable from the back of the module.

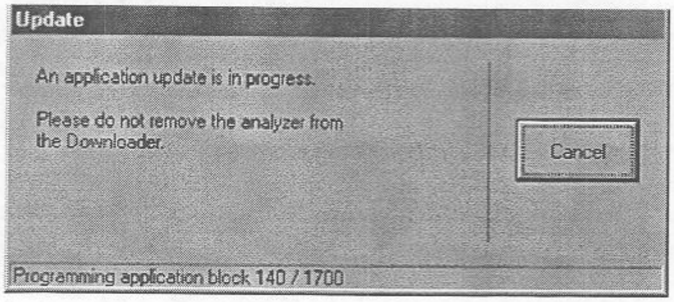
2) Plug the upgrade cable into the back of the module.

Waiting for module...(COM1)

---

12 During the update the following screens will be displayed.

For the i-STAT 1 Analyzer:

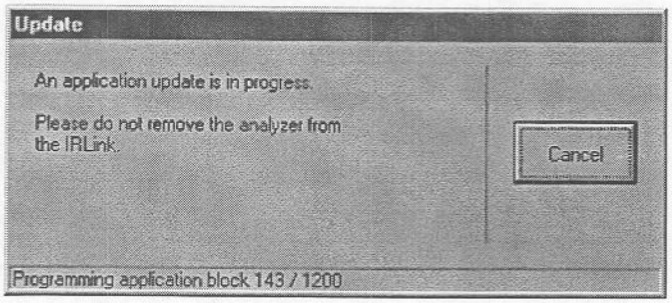


An application update is in progress.

Please do not remove the analyzer from the Downloader.

Programming application block 140 / 1700

For the i-STAT Portable Clinical Analyzer:

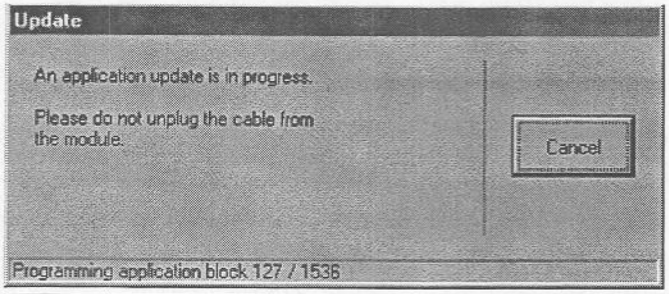


An application update is in progress.

Please do not remove the analyzer from the IRLink.

Programming application block 143 / 1200

For the Blood Analysis Module:

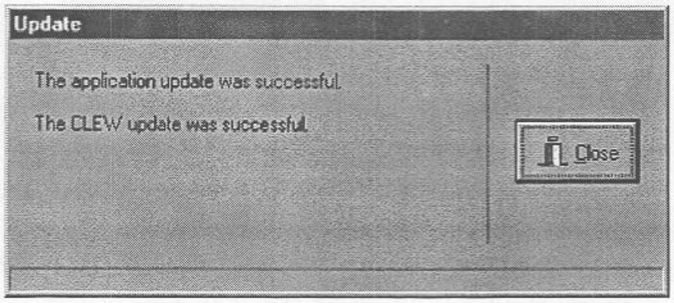


An application update is in progress.

Please do not unplug the cable from the module.

Programming application block 127 / 1536

Do not move an analyzer or unplug a Blood Analysis Module until the following screen is displayed:



The application update was successful.

The CLEW update was successful.

13 Click on Close. The JammLite program will return to step 7 to allow any selections to be changed before starting another update. If no other update is required, click on Exit.

Verifying the Update

14 Run an external Electronic Simulator on updated analyzers and check the Analyzer Status page for the new Application software and/or CLEW.

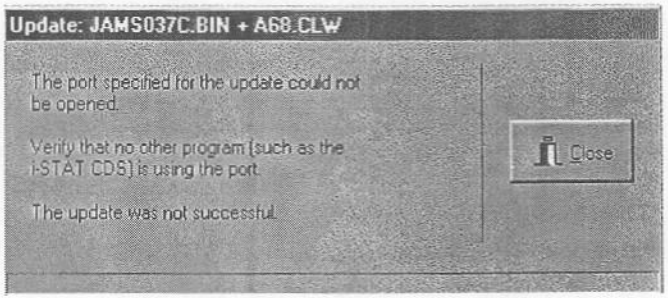
Important! Restarting the Central Data Station

15 When all analyzers have been updated, re-start the Central Data Station software, update the Customization Profile(s) with the new CLEW and enable Customization if desired.

Troubleshooting

COM port to be used for the update is not listed in the Port List. Only those ports not currently in use are listed. Exit the JammLite program and ensure that there are no other programs running which may be using the port (such as the Central Data Station). Restart the JammLite program to determine if the port is now listed.

If an error is encountered during the update, an error screen will be displayed. (**Note:** application and CLEW on Update Line are used only as an example.)



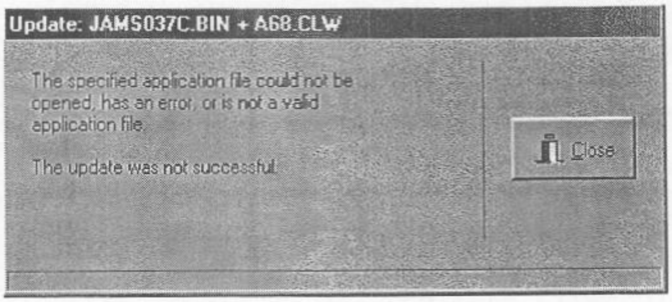
Update: JAMS037C.BIN + A68.CLW

The port specified for the update could not be opened.

Verify that no other program (such as the i-STAT CDS) is using the port.

The update was not successful.

JammLite must be the only program attempting to use the selected port. If this message is displayed, ensure that no other programs are using the port and that the correct port was selected.

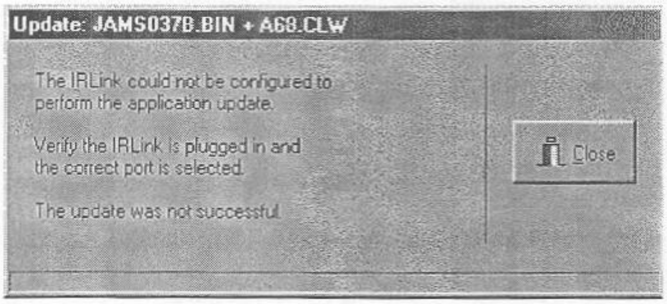


Update: JAMS037C.BIN + A68.CLW

The specified application file could not be opened, has an error, or is not a valid application file.

The update was not successful.

If this message is displayed, ensure that all other programs are closed and that the proper application was selected before re-attempting the update.



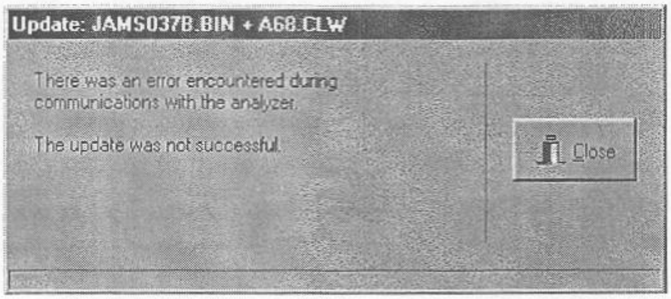
Update: JAMS037B.BIN + A68.CLW

The IRLink could not be configured to perform the application update.

Verify the IRLink is plugged in and the correct port is selected.

The update was not successful.

The JammLite program could not configure the IR Link. Verify that the IR Link is connected to the COM port, that the LED on the IR Link is red and the proper port is selected.

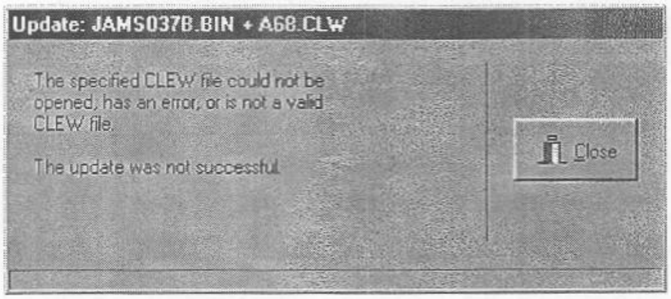


Update: JAMS037B.BIN + A68.CLW

There was an error encountered during communications with the analyzer.

The update was not successful.

There was a problem sending the update information to the instrument. Ensure the instrument is located properly in the IR Link or Downloader, and that it is not removed before the update is completed.

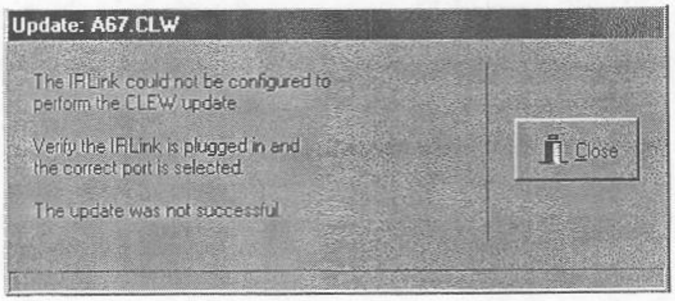


Update: JAMS037B.BIN + A68.CLW

The specified CLEW file could not be opened, has an error, or is not a valid CLEW file.

The update was not successful.

Ensure that all other programs are closed and that the correct CLEW is selected before re-attempting the update.



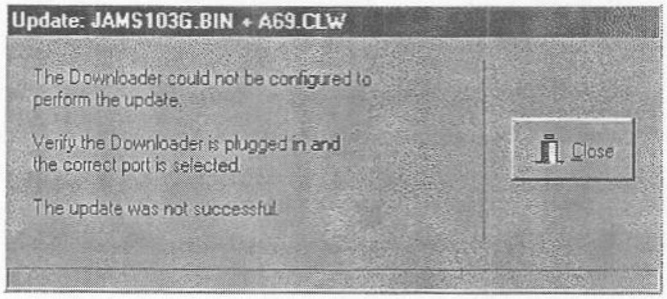
Update: A67.CLW

The IRLink could not be configured to perform the CLEW update.

Verify the IRLink is plugged in and the correct port is selected.

The update was not successful.

The JammLite program could not configure the IR Link. Verify that the IR Link is connected to the COM port, the LED on the IR Link is red, and the proper port is selected.



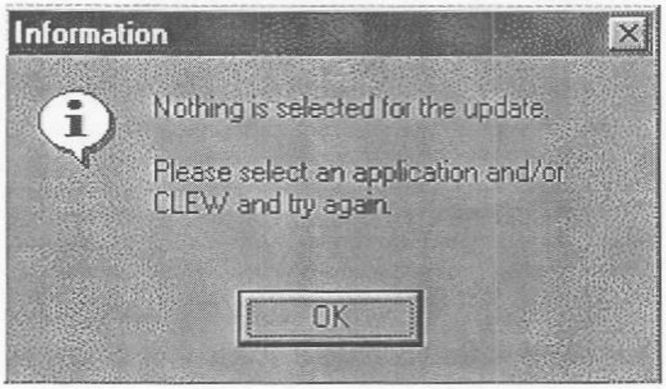
Update: JAMS103G.BIN + A69.CLW

The Downloader could not be configured to perform the update.

Verify the Downloader is plugged in and the correct port is selected.

The update was not successful.

The JammLite program could not configure the Downloader. Verify that the Downloader is connected to the COM port, the Downloader is powered, and that the proper port is selected.



Information

Nothing is selected for the update.

Please select an application and/or CLEW and try again.

Either an Application or a CLEW (or both) must be selected prior to clinking on the Update button.

Quality Check Code 13 - Invalid Expired CLEW after on-line customization is restored

If this quality check code occurs after successfully downloading new software and restoring on-line customization, the CLEW has not been updated to the new version in the Customization Profile.

i-STAT 1 Analyzer

Step	Action
1	Any updated analyzer can be used as the sending analyzer. Select the Utility option under the Administration Menu on the sending analyzer. The Utility menu can be password protected. Enter the password or press the Enter key if no password has been specified. From the Utility Menu select **1-Send Software**. Select **1 – JAMS and CLEW** or **2-CLEW** as required for the update. The message "Waiting to Send" will be displayed.
2	Ensure that the receiving analyzer is off.
3	Place the sending and receiving analyzers facing each other on a flat surface about 30cm (1 foot) apart and align their IR windows. Move one analyzer toward the other until the message "Sending…" is displayed on the sending analyzer and a scrolling banner appears on the receiving analyzer.
4	Do not move the analyzers until the "Sending…" message is removed from the sending analyzer's display. The sending analyzer will return to the Send Software option and will display the result of the last software update as "Successful" or "Unsuccessful."
5	Select the Analyzer Status option under the Administration menu on the receiving analyzer and check that the new JAMS and/or CLEW are listed.

12

Step	Action
1	Any updated analyzer can be used as the Sending Analyzer. Run the external Electronic Simulator on the Sending Analyzer.
2	Transmit all data from the analyzer being updated (the Receiving Analyzer) to the Central Data Station. Data stored in the handheld analyzer will be lost after an application software update.
3	With the Simulator test results showing on the display of the Sending Analyzer, press and hold the DIS key and press the soft key for MENU. This displays the Utility Menu.
4	In the Utility Menu, select 3 - Send Software. The display will show the JAMS version and the CLEW in this analyzer. Verify that these are the appropriate versions. The analyzer screen will also say "Waiting to send".
5	Set both analyzers on a flat surface and align the Infrared Light-Emitting Diode (IR LED) windows so they directly face each other. (Refer to the analyzer picture on page 2-2 of the i-STAT System Manual for the location of the IR LED.)
6	On the Receiving Analyzer, make sure the display is off. Press and hold the * key and press the DIS key. The Sending Analyzer will begin sending software to the Receiving Analyzer. The display on the Sending Analyzer will change from "Waiting to send" to "Sending...", and a countdown bar will be displayed.
	Do not move the analyzers while the software is being sent.
7	When the display of the Sending Analyzer changes back to the Electronic Simulator result, the sending of software is complete. Do not press the DIS key on the Receiving Analyzer. Run the Electronic Simulator on the Receiving Analyzer.
8	To update software in another analyzer, repeat these instructions from Step 2.

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Windows is a registered trademark of Microsoft Corporation.

Updating Analyzer Software: JAMMIT Utility

This Technical Bulletin contains the instructions for updating application software and CLEW in the i-STAT Portable Clinical Analyzer and Philips Medical Systems Blood Analysis Module. Unless you have a Central Data Station 3.1 or a PC with a Windows software below 95, we recommend that you use the JAMMLITE Utility rather than this JAMMIT Utility to update your analyzers and Blood Analysis Modules. If you have any questions, please call i-STAT Technical Support at (877) 529-7185.

SETTING UP THE COMPUTER

If using an i-STAT Central Data Station

if using an i-STAT Central Data Station (CDS) to update the Analyzers, follow the steps below for setting up the computer:

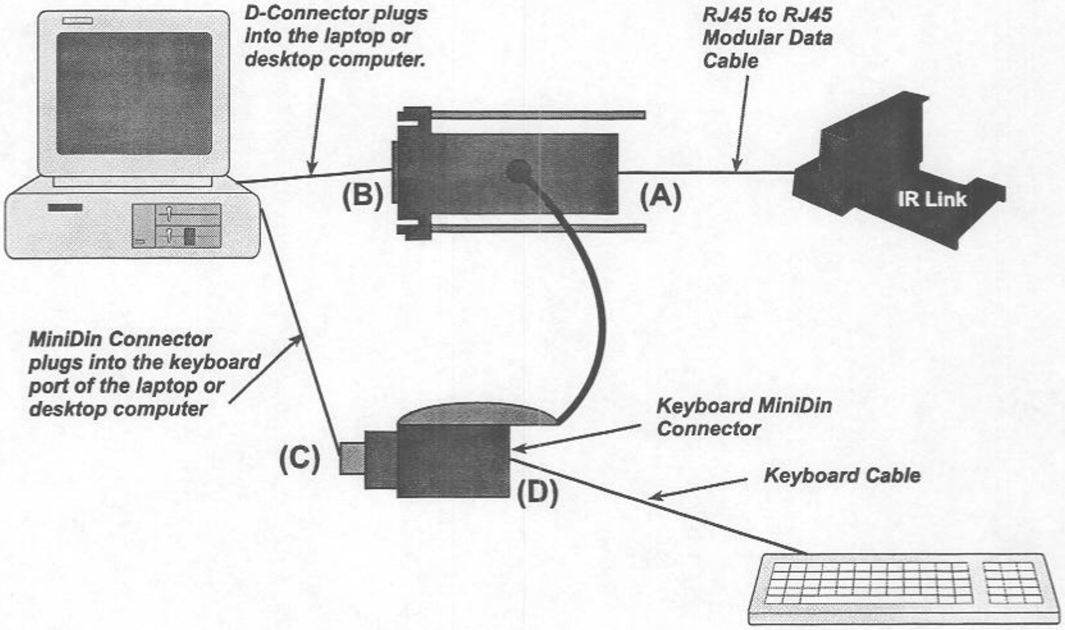
Step	Action
1	If updating handheld analyzers, transmit all data from the handhelds to the CDS. Data stored in a handheld analyzer will be lost after an application software update.
⚠ **Attention:**	If the Analyzer Customization Profile Utility is enabled in your Central Data Station, disable it prior to starting this process. The profile can be saved for restoration. For additional information on doing this, refer to the i-STAT Technical Bulletin, "Instructions for the Analyzer Customization Profile Utility" or in newer manuals, "Customization Utility" in the Central Data Station 4 section. Once Analyzers are updated, the function to restore the profile can be used to re-enable on-line customization, if desired. **However, be sure to first select the new CLEW in the profile.**
2	Connect a Modular Data Cable to the COM5 port on the back of the CDS. If your Central Data Station has one quad card (four ports for data cables), COM 5 is the innermost port closet to the fan. If your CDS has two quad cards, COM 5 is the innermost port on the bottom row of ports. If updating handheld analyzers, connect an IR Link to the opposite end of the cable.
3	Click on *Exit* to close the Central Data Station application.
4	Exit the Windows application following the instructions below for your platform: Windows 3.1 platform: Click on FILE and then EXIT in the Program Manager. Windows 95/98 platform: Click the Start button, select Shut Down..., then select Restart in DOS mode. Windows NT platform: Click the Start button, select Programs, then select Command Prompt. With Windows 95/98 and NT platforms, you will be at the C:\WINDOWS prompt on exiting. Return to the root directory by typing cd\ and pressing the **Enter** key.

5	Place the diskette labeled “Software for Analyzers” into the A: drive.
6	At the C:\> prompt, type **A:TRANSFER** and press the ENTER key. Wait for the DOS prompt C:\BINS> to appear. Ignore any “File Not Found” or “Directory Already Exists” messages that may appear.
7	At the C:\BINS> prompt, type **JAMMIT** and press the ENTER key. The i-STAT Configuration Utility will appear.
8	Proceed with the section of this document titled “Downloading to an Analyzer”.

If you are using any other IBM PC compatible/ Point-of-Care Central Workstation

If using any other IBM PC compatible to update the analyzers, follow the steps below for setting up the computer:

Step	Action
1	If updating handheld analyzers, transmit all data from the handhelds to the CDS. Data stored in a handheld analyzer will be lost after an application software update.
2	Connect a Modular Data Cable to one of the 9-pin connector COM ports on the PC using the power adapter according to instructions supplied with it or the picture below. If updating handheld analyzers, connect an IR Link to the opposite end of the cable.
3	Exit all applications. You must be at the MS DOS prompt. (See Step 4 under *“If Using an i-STAT Central Data Station.”*)
4	Place the diskette labeled “Software for Analyzers” into the A: drive.
5	At the C:\> prompt, type **A:TRANSFER** and press the ENTER key. Wait for the DOS prompt C:\BINS> to appear. Ignore any “File Not Found” or “Directory Already Exists” messages that may appear.


D-Connector plugs into the laptop or desktop computer.
RJ45 to RJ45 Modular Data Cable
IR Link
(B)
(A)
MiniDin Connector plugs into the keyboard port of the laptop or desktop computer
Keyboard MiniDin Connector
Keyboard Cable
(C)
(D)

6	At the C:\BINS> prompt, type **JAMMIT** and press the ENTER key. The i-STAT Configuration Utility will appear.
7	Using the UP/DOWN arrow keys, highlight **Utility Setup** and press the ENTER key.
8	Using the UP/DOWN arrow keys, highlight **COM Port**. Using the RIGHT/LEFT arrow keys, select 1 or 2, depending on where the 9-pin connector is connected.
9	Using the UP/DOWN arrow keys, highlight **Return to Main Menu** and press the ENTER key.
10	Proceed with the section of this document titled "Downloading to an Analyzer".

DOWNLOADING SOFTWARE TO AN ANALYZER

Downloading to a handheld analyzer

Follow the steps below to download software to a handheld analyzer:

Step	Action
1	Highlight **Software** and press the ENTER key. The window **Select Files to Download** appears. The menu items **Application** and **CLEW** will automatically be set to the newest version.
2	Confirm the setting for **Application** and **CLEW** against the Product Update accompanying the diskette. If, under specific instruction from i-STAT, different versions are to be downloaded, highlight the menu item you are to change using the UP/DOWN arrow keys and use the LEFT/RIGHT arrow keys to set the proper version. **Note:** If the software upgrade is only a **CLEW**, select "None" for application.
3	Highlight **Download Selection** and press the ENTER key.
4	Follow the instructions on the computer screen. **Do not move the analyzer while download is in progress. Do not press the DIS key. When download is complete, run the Electronic Simulator in the Analyzer.** **Note:** On the handheld status page, the Application name is displayed on the line labeled **Ver:** and the CLEW is displayed on the line labeled **CLEW**.
5	After the update of all handheld analyzers is complete, the function to restore the Customization Profile can be used to re-enable on-line customization if desired. **Be sure to select the new CLEW in the profile first. Failure to do this will result in Quality Check Code 13.**

Downloading to a Blood Analysis Module

Follow the steps below to download software to a Blood Analysis Module:

Step	Action
1	Highlight **Utility Setup** and press ENTER key. The window Utility Setup appears.
2	Using the UP/DOWN arrow keys, highlight **Analyzer**. Using the RIGHT/LEFT arrow keys, select **HP Blood Analysis Module.**
3	Highlight **Return to Main Menu** and press the ENTER key.

4 Highlight **Software** and press the ENTER key. The window **Select Files to Download** appears. The menu items **Application** and **CLEW** will automatically be set to the newest version.

5 Confirm the setting for **Application** and **CLEW** against the Product Update accompanying the diskette. If, under specific instruction from i-STAT, different versions are to be downloaded, highlight the menu item you are to change using the UP/DOWN arrow keys and use the LEFT/RIGHT arrow keys to set the proper version.

Note: If the software upgrade is only a **CLEW**, select "None" for application.

6 Highlight **Download Selection** and press the ENTER key.

7 Follow the instructions on the computer screen. **Do not unplug the module while the download is in progress.**

Note: When the module is returned to a monitor, the CLEW can be viewed in the Blood Analysis Setup screen.

8 After the update of all modules is complete, the function to restore the Customization Profile can be used to re-enable on-line customization if desired. Be sure to select the new CLEW in the profile first.

Sending Software from handheld to handheld

To send software from one handheld analyzer to another, follow the instructions below:

Step Action

1 Any updated analyzer can be used as the **Sending Analyzer**. Run the external Electronic Simulator on the Sending Analyzer.

2 Transmit all data from the analyzer being updated (the **Receiving Analyzer**) to the Central Data Station. Data stored in the handheld analyzer will be lost after an application software update.

3 With the Simulator test results showing on the display of the Sending Analyzer, press and hold the DIS key and press the soft key for MENU. This displays the Utility Menu.

4 In the Utility Menu, select 3 - **Send Software**. The display will show the JAMS version and the CLEW in this analyzer. Verify that these are the appropriate versions. The analyzer screen will also say "Waiting to send".

5 Set both analyzers on a flat surface and align the Infrared Light-Emitting Diode (IR LED) windows so they directly face each other. (Refer to the analyzer picture on page 2-2 of the i-STAT System Manual for the location of the IR LED.)

6 On the Receiving Analyzer, make sure the display is off. Press and hold the * key and press the **DIS** key. The Sending analyzer will begin sending software to the Receiving Analyzer. The display on the Sending Analyzer will change from "Waiting to send" to "Sending...", and a countdown bar will be displayed.

Do not move the analyzers while the software is being sent.

7 When the display of the Sending Analyzer changes back to the Electronic Simulator result, the sending of software is complete. **Do not press the DIS key. Run the Electronic Simulator on the Receiving Analyzer.**

8 To update software in another analyzer, repeat these instructions from Step 2.

TROUBLESHOOTING

Error message relating to the IR Link	If you are using any other IBM PC compatible computer, another application relating to the may be monopolizing the COM port. Close all other open applications. Ensure the utility is set to use the proper COM port in the Utility Setup option from the main menu. If the setting is proper, quit the Utility, turn off the computer, unplug and replug the IR Link, restart the computer, and try the download again.
UPDATE .cfg not found	Ensure you run A:TRANSFER from an i-STAT software diskette. Ensure you run **JAMMIT** from C:\BINS>
Block count stops incrementing	If the block count on the status line of the computer screen stops incrementing for more than 10 seconds during a download, press the **Esc** key to abort the download. If updating an handheld analyzer, take it out of the IR Link, remove and replace the batteries to reset. If updating a Blood Analysis Module, unplug the cable and plug it in again. This can happen if you try to run **JAMMIT** under Microsoft Windows (Windows 3.1 or 95/98 platform). You must exit Windows and run the program in the DOS mode. Try the download again.
Nothing happens OR Handheld displays results or error message when *DIS is pressed as prompted	Remove and replace the batteries to reset the handheld. Ensure the handheld display is off. Place the handheld back in the cradle, ensure it is properly seated. Press and hold the * key for 2 seconds, then press the **DIS** key while keeping the * key pressed.
LEDs on the module are OFF	Possibly the cable or the COM port is defective. Try another cable and/or configure another port to "HP Blood Analysis Module" and try again.
Quality Check Code 13 - Invalid Expired CLEW after on-line customization is restored	If this quality check code occurs after successfully downloading new software and restoring on-line customization, the CLEW has not been updated to the new version in the Customization Profile. Refer to i-STAT Technical Bulletin "Instructions for the Analyzer Customization Profile Utility.

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i-STAT

Technical Bulletin

Troubleshooting: Caution!

This Technical Bulletin or a copy of the cautionary statement below should be placed in the Troubleshooting section of your i-STAT System Manual: Section 6 in the i-STAT® System Manual (for the Portable Clinical Analyzer) or Section 19 in the i-STAT®1 System Manual.

Caution! DO NOT OPEN THE ANALYZER, or any other i-STAT product, or perform any unauthorized procedures. Opening any i-STAT product, including analyzer, Electronic Simulator, printer or communication device, in attempt to repair it or resolve a problem may cause erroneous results. If the troubleshooting procedures found in this manual or requested by an i-STAT support specialist do not resolve the problem, the product must be returned to i-STAT for repair.

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i-STAT

Technical Bulletin

Proficiency Testing on the i-STAT® System

PROFICIENCY TESTING

CLIA regulation *Subpart H – Participation in Proficiency Testing* requires a laboratory to enroll in a proficiency testing program approved by the Health Care Financing Administration (HCFA) for its primary test system or that system used at its primary site. The laboratory must participate successfully as defined by the criteria defined in *Subpart I – Proficiency Testing Programs.*

A primary testing system is defined as the only method or the primary method for performing and reporting tests under a CLIA certificate. The i-STAT System is a primary testing system when:

- A hospital has separate CLIA certificates for the main laboratory and point of care testing;
- A hospital owns a clinic, same-day surgery, kidney dialysis unit, etc., which requires a separate CLIA certificate;
- The i-STAT System is the hospital's primary laboratory testing system; or
- The i-STAT System is the main testing system in a physician's office, skilled nursing facility, unaffiliated patient transport service, home-healthcare agency, etc.

Proficiency testing (PT) programs must provide three separate shipments during the year that include five challenges for each analyte or test. Laboratories must handle samples as they would patient samples and return the results within a specified time to the provider for grading.

THE i-STAT SYSTEM

The i-STAT System consists of any number of i-STAT Portable Clinical Analyzers, i-STAT 1 Analyzers and Phillips Medical Systems Blood Analysis Modules (collectively known as "Analyzer"). All Analyzers that pass the Electronic Simulator test are equivalent. Therefore, PT samples can be tested on any Analyzer that has passed the Electronic Simulator test.

PT PROGRAMS FOR THE i-STAT SYSTEM

There are several national HCFA approved PT program providers such as the College of American Pathologists (CAP), the American Association of Bioanalysts (AAB), and the American Proficiency Institute (API). Several states have HCFA approved PT programs as well. Each of these providers has several PT surveys to choose from. In general, aqueous-based PT surveys are recommended.

Certain PT survey samples are not compatible with the sensors and may contain interfering substances that could affect results. Fluorocarbon samples for blood gases and fixed-cell samples for hematocrit are not compatible with the sensors.

WHEN USING AN AQUEOUS SAMPLE different results can be expected from thermally controlled cartridges using JAMS software, thermally controlled cartridges using MINT software and non-thermally controlled cartridges. Therefore, it is important to code correctly for thermally controlled (JAMS or MINT) and non-thermally controlled samples when reporting PT results (see below). For those surveys that do not yet have separate groupings for MINT software it is recommended that standard JAMS software be used. All cartridge types have equivalent results when using a whole blood sample.

The i-STAT System allows users the option to choose special standardization settings and alternate versions of operating software. Specifically for hematocrit analysis, it is recommended that users measure proficiency testing samples on analyzers that are customized for K3EDTA rather than K2EDTA and **DO NOT** apply CPB sample type.

CAP SURVEYS PROGRAM

Instrument Codes

The proper code is determined not by the i-STAT Analyzer but rather by the specific i-STAT Cartridge used to analyze the sample.

Instrument Codes Notes:

- The CAP AQ and AQ2 (Critical Care Aqueous Blood Gas with Chemistry) surveys are recommended for the i-STAT System. For ACT, the CAP CTI (Metronic) survey is recommended.
- For consistency of results across sites, hematocrit results should be reported using an analyzer customized for K3EDTA. On the i-STAT1 Analyzer, the PT pathway is customized for K3EDTA. If the i-STAT Portable Clinical Analyzer used to assay a PT sample is customized for K2EDTA, the displayed hematocrit results should be divided by 1.0425 before reporting to CAP.
- For consistency of results across sites, do not select CPB as sample type for PT samples.
- According to the AQ and AQ2 survey instructions, PO_2 results should not be corrected for barometric pressure. The barometric pressure should be reported with the uncorrected results. Barometric pressure can be recorded from the Status page after results are displayed.
- For the CTI survey, samples are reconstituted with calcium chloride supplied by the user.

Cartridge Type

37° cartridges
G3+, EG6+, EG7+, CG8+, CG4+, and CREA

Non 37° cartridges
G, E3+, EC4+, 6+, EC6+ and EC8+

Instrument Codes

i-STAT 37° cartridges: 1039

i-STAT 37° cartridges/MINT software: 1828

i-STAT non 37° cartridges: 1262

i-STAT non-37° cartridges/MINT software: 1829

i-STAT ACT cartridges: 2085

College of American Pathologists
325 Waukegan Road
Northfield, IL 60093-2750
800-323-4040 or 847-832-7000

AAB PROFICIENCY TESTING SERVICE

Method Code for ACT (Activated Clotting Time): 600

American Association of Bioanalysts (AAB)
AAB Proficiency Testing Service
205 West Levee St.
Brownsville, Texas 78520
800-234-5315

API PROFICIENCY TESTING PROGRAM

i-STAT Proficiency Testing Program

Indicate thermal or non-thermal for each analyte.

thermal (37°) cartridges
G3+, EG6+, EG7+, CG8+, CG4+, and CREA

non thermal (non 37°) cartridges
G, E3+, EC4+, 6+, EC6+ and EC8+

American Proficiency Institute
1159 Business Park Drive
Traverse City, MI 49686
800-333-0958

WSLH - WISCONSIN STATE LABORATORY OF HYGIENE

Method Code for Activated Clotting Time (CT): **3671**

Method Code for thermal (37°) cartridges: **3671**
G3+, EG6+, EG7+, CG8+, CG4+, and CREA

Method Code for non-thermal (non 37°) cartridges: **3670**
G, E3+, EC4+, 6+, EC6+ and EC8+

Wisconsin State Laboratory of Hygiene
465 Henry Mall Room 402
Madison, WI 53706
800 462-5261

Technical Bulletin

Compensation for Extreme Altitude and Barometric Pressure on PO_2 Results in Aqueous Materials

What is barometric pressure?

Barometric pressure is a measure of atmospheric pressure and is influenced by changes in altitude and weather conditions. The atmospheric pressure is approximately 760 mmHg at sea level. Oxygen constitutes approximately 20.9% of this pressure or 159 mmHg at sea level.

Oxygen pressure and aqueous solutions

The partial pressure of oxygen in a solution will change as it attempts to equilibrate to the surrounding ambient pressure. The rate of change is faster in aqueous material than in whole blood samples due to the absence of red blood cells containing hemoglobin which bind oxygen molecules. This is of practical significance when testing aqueous materials on blood gas analyzers as there will be a detectable shift in the partial pressure of oxygen in the sample as it attempts to equilibrate to the flowpath.

Compensation factors for the i-STAT System

The ranges for i-STAT aqueous materials are established for the degree of equilibration which occurs in the i-STAT cartridge at or near sea level. The results for aqueous materials such as the i-STAT Calibration Verification Set, i-STAT Controls, and aqueous proficiency/external quality control materials* can be easily corrected for higher altitude environments. The formulas below should be applied to the observed PO_2 results prior to comparing them to the published acceptable range for the level of material:

FOR PO_2 VALUES BELOW 150 mmHg - Controls: Levels 1, 2, 3
Calibration Verification: Levels 1, 2, 3

$$PO_2\text{Corrected} = PO_2\text{Observed} + (0.067 \times (760 - \text{BP}))$$

where BP is the barometric pressure reading from the analyzer status page.
Approximate change: For every decrease of 15 mmHg in pressure (from 760 mmHg), add 1 mmHg to reading.

FOR PO_2 VALUES ABOVE 150 mmHg - Calibration Verification: Levels 4, 5

$$PO_2\text{Corrected} = PO_2\text{Observed} + (0.029 \times (760 - \text{BP}))$$

where BP is the barometric pressure reading from the analyzer status page.
Approximate change: For every decrease of 35 mmHg in pressure (from 760 mmHg), add 1 mmHg to reading.

*** Check the instructions for the proficiency or external quality control survey to see if corrected or uncorrected PO_2 results should be reported. The survey provider may request the uncorrected results and BP taken at the time of the measurements.**

i-STAT

Technical Bulletin

Calibration Verification for Analytes on the Portable Clinical Analyzer

Purpose

Calibration Verification is a procedure intended to verify the accuracy of results over the entire measurement range of a test. The performance of this procedure at defined intervals may be required by regulatory or accreditation bodies. While the Calibration Verification Set contains five levels, verification of the measurement range could be accomplished using the lowest, highest and mid levels.

Calibration Verification Solutions for Cartridges

A five-level Calibration Verification Set is available to verify the calibration of i-STAT cartridges throughout the reportable ranges for:

- Sodium
- Potassium
- Chloride
- Ionized Calcium
- pH
- $P\mathrm{CO}_2$
- $P\mathrm{O}_2$
- Glucose
- Lactate
- BUN/Urea
- Creatinine

There are four 1.7mL glass ampules of each level in the set.

Storage

Refrigerated storage at 2 to 8 °C (35 to 46°F) should be maintained until the printed expiration date on the box and ampule labels. Calibration Verification fluids may also be stored at room temperature for up to 5 days (20 to 30 °C or 68 to 86°F). Prolonged storage at temperatures greater than 30 °C (86°F) may cause changes in the values of some analytes. Do not use beyond the expiration date on the box and ampule labels.

Ampule Use

When using cartridges that contain sensors for pH, $P\mathrm{CO}_2$, $P\mathrm{O}_2$ and ionized calcium, a separate ampule must be used for each cartridge being tested. If these sensors are not present, the contents of one ampule may be used to fill more than one cartridge as long as the cartridges are filled and inserted into an analyzer within 10 minutes of opening the ampule.

Best Results

For best results, ampules, cartridges and analyzers should be at the same temperature.

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Art: 715061-00A
Rev. Date: 06/10/02

Before Use

i-STAT Calibration Verification solutions require different temperature stabilization times depending on whether or not oxygen is to be measured. If oxygen is to be measured, equilibrate the ampule for 4 hours. If not, equilibrate the ampule to room (ambient) temperature for 30 minutes.

Procedure

Step	Action
1	Immediately before use, shake the ampule vigorously for 5 to 10 seconds to equilibrate the liquid and gas phases. To shake, hold the ampule at the tip and bottom with forefinger and thumb to minimize increasing the temperature of the solution. If necessary, tap the tip of the ampule to send solution back into the bottom section of the ampule.
2	Protect fingers with gauze, tissue or glove, or use an ampule breaker to snap off the tip of the ampule at the neck.
3	Immediately transfer the solution from the ampule into a capillary tube or syringe, and then immediately transfer the solution into a cartridge.
4	Immediately seal the cartridge and insert it into an analyzer – it is important not to expose the solution to room air since this will alter the results.

Note: Since aqueous based solutions such as controls lack the buffering capabilities of whole blood, the transfer process from ampule to cartridge must be more expedient than with a patient sample.

Transfer with Capillary Tube

When using a capillary tube (fresh capillary tubes with sufficient fill capacity are recommended), fill from the bottom of the ampule.

Avoid drawing solution from the surface by placing a finger over the far end of the tube as it is inserted into the ampule.

Once the open end of the tube rests at the bottom of the ampule, uncover the other end to allow filling by capillary action.

Transfer with Syringe

When using a syringe (fresh 1cc or 3cc sterile syringes with 16 - 20 gauge needles are recommended), slowly draw approximately 1mL of solution from the bottom of the ampule.

If air is trapped between the leading edge of the solution and the plunger, do not invert the syringe to expel it; this will not affect solution near the front of the syringe.

If air bubbles are continually drawn into the syringe, or if a bubble is trapped near the tip of the syringe, discard the ampule and syringe and use a fresh ampule and syringe.

Expel one or two drops from the syringe before filling the cartridge.

Acceptable Criteria

Target values (determined by testing multiple ampules of each level using multiple lots of i-STAT cartridges with analyzers that have passed the Electronic Simulator test) and acceptable ranges for the means of 3 replicates are printed on a value assignment sheet included with each Calibration Verification Set.

Calibration throughout the reportable range of each analyte is verified if each average value falls within the corresponding range in the value assignment sheet.

To calculate the average value, add the three results obtained for each test in each level and divide by three. If an average value is not in range, inspect the results for a statistical outlier.

If a result is determined to be an outlier, test a fourth cartridge using the fourth ampule included in the Calibration Verification Set, and recalculate the average value after replacing the outlier with the new result. If the average value is still outside the acceptable range or if there is more than 1 outlier in the data set, troubleshooting may be required.

Note: If the Calibration Verification Set is to be used to assess linearity, plot the average value against the mean value of the acceptable range. The concentrations of analytes in the Calibration Verification Set are not intended or prepared to be equally spaced.

If testing at extreme altitude refer to the Technical Bulletin: Compensation for Extreme Altitude and Barometric Pressure on PO_2 Results in Aqueous Controls.

Procedure for Cartridges

Calibration Verification and linearity solutions can be tested via a test path accessed from the Utility menu on the i-STAT Portable Clinical Analyzer. (This test path is not available on the BAM.) The same standardization CLEW is used to calculate both patient sample results and calibration verification/linearity sample results. The difference is that in the Calibration Verification test path, the application software does not apply measurement range flags so that results for samples below and above the measurement ranges can be reported.

Note: Because the Utility menu also includes a Clear Stored Results option, it may not be wise to give end users access to the Utility menu.

The ID # (corresponds to Patient ID # in the standard test path) can be used to identify these samples and the cartridge lot number. Note that each of the five levels in the i-STAT Calibration Verification kit has its own lot number. The lot number for Level 1 can be used to identify the kit or each lot number can be used to identify each sample. The letters in the Calibration Verification and cartridge lot numbers can be ignored. For example: Cal Ver level 1 and lot number 1109 plus cartridge lot 02089: 1110902089.

Note: Samples should be prepared and ready to test before starting this procedure since the analyzer will wait for only 45 seconds after the "INSERT CARTRIDGE" message is displayed before powering down.

Display	Action	Analyzer Response
OFF (blank) or ON with a result displayed.	Insert Electronic Simulator	Electronic Simulator test cycle will commence.
Electronic Simulator PASS result displayed.	Hold down the DIS key and press the MENU soft key.	Utility Menu will be displayed.
Utility Menu 1 Clear Stored Results 2 Printer Setup 3 Send Software 4 Cal Ver 5 Proficiency	Press 4 for Cal Ver	Insert cartridge prompt will be displayed.
Cal Ver INSERT CARTRIDGE	Insert filled cartridge into analyzer cartridge port. If the display turns OFF before the cartridge is inserted, turn the analyzer ON using the DIS key. You must re-enter the Utility menu and select the Cal Ver option before inserting the filled cartridge.	Test cycle will commence. If at any point during the test cycle a quality check fails, the test cycle will halt and a message will be displayed indicating the condition and the corrective action.
_ _ _ _ _ _ _ Operator #, ENT	Enter Operator ID and press ENT.	
#_ _ _ _ _ _ _ Repeat #, ENT	Repeat Operator ID and press ENT.	Repeat of Operator ID entry may not be required depending on analyzer customization settings. If the repeated ID does not match the original, the ID must be re-entered.

#_ _ _ _ _ _ _ _ _ _ _ _ Repeat #, ENT	Repeat the sample ID number and press ENT.	Repeat of sample ID entry may not be required depending on analyzer customization settings. If the repeated ID does not match the original, the ID must be re-entered.
Select Tests (Available tests will be dependent on cartridge type).	Use the number keys to select tests to be reported. (Press a number key a second time to deselect a test.) Press PAGE key when all desired tests are selected.	Test selection may not be required depending on analyzer customization settings.
Chart Page	Use the number and ENT keys to enter test information if desired. Press PAGE key when all information entry is complete.	Automatic display of the Chart Page is dependent on analyzer customization settings.
Results Displayed	If results are not displayed, but RESULTS READY message is visible, press the PAGE key until the results page is shown. Remove the cartridge and discard in a biohazard container. Print or transcribe results.	Analyzer unlocks cartridge and is ready for another cartridge. If another cartridge is inserted into the analyzer without pressing DIS and MENU, it will be run as a patient sample. To run another Cal Ver sample continue to next instruction.
Results Displayed	To run another Cal Ver sample, hold down the DIS key and press the MENU key.	Utility Menu will be displayed.
Utility Menu 1 Cal Ver 2 Proficiency	Press 1 for Cal Ver	Insert Cartridge prompt will be displayed. Follow sequence from the Insert Cartridge screen as shown above to complete the test cycle.

Troubleshooting Cartridge Tests

See also the Control Out-of-Range paragraph in the Routine Care, Troubleshooting & Technical Information section in this manual.

i-STAT

Technical Bulletin

Proficiency Testing and External Quality Control Testing on the Portable Clinical Analyzer

Purpose

Samples from proficiency testing or external quality control providers can be used to assess consistency of results for a particular method or system across testing sites. Due to matrix effects and additives, these samples should not be used as an indication of the system's true accuracy.

Selection of a Provider

The i-STAT System is designed to measure fresh whole blood samples. Matrix effects and interfering substances can be expected when measuring non-whole blood samples. In the USA, see the Technical Bulletin "Proficiency Testing and the i-STAT System" for recommended providers. For other countries, the following points should be considered when selecting and testing external quality control samples:

- Aqueous samples intended to assess blood gases will not be measured by the i-STAT System unless electrolytes, or at least sodium, are present.
- Fluorocarbon samples are not compatible.
- Preserved-cell samples, other than Meter Trax (Hematronix, Inc) whole blood controls for glucose and hematocrit, are not compatible. (The i-STAT System will report only hematocrit for Meter Trax controls.)
- Aged serum and lyophilized serum may contain degradation products or preservatives that interfere with the measurements.
- Matrix effects between aqueous-based and protein-based samples may cause results from the i-STAT System to differ from reference methods or other comparative methods.

Procedure for Cartridges

Proficiency Testing (PT) and External Quality Control (EQA) samples can be tested using the patient sample test path or the test path accessed from the Utility menu on the Portable Clinical Analyzer. (This test path is not available on the BAM.) The same CLEW (standardization software) is used in both test paths. However, in the test path accessed via the Utility menu, hematocrit results are calculated using coefficients for K3EDTA even if the analyzer is customized for K2EDTA. This ensures that hematocrit results are consistent across all sites. Also, if star-outs occur frequently when using the patient sample test path, they may be avoided by using the proficiency testing test path.

If using a BAM to test PT or EQA samples, the BAM should be customized for K3EDTA.

Important! In order for hematocrit results to be consistent across all sites, do not select the CPB sample type.

The ID # (same as Patient ID # in standard test path) can be used to identify these samples and the lot number of cartridges used. For example, if the sample identification number is 12 and the cartridge lot number is M02089B, the ID# would be 1202089.

Note: Because the Utility menu also includes a Clear Stored Results option, it may not be wise to give end users access to the Utility menu. The person responsible for the PT or EQA program could access the Utility menu and select **5 – Proficiency** on the analyzer before presenting the analyzer and the sample to the end user.

Note: Sample should be prepared and ready to test before starting this procedure since the analyzer will wait for only 45 seconds after the "INSERT CARTRIDGE" message is displayed.

DISPLAY	STEP	ANALYZER RESPONSE
OFF (blank) or ON with a result displayed.	Insert Electronic Simulator	Electronic Simulator test cycle will commence.
Electronic Simulator PASS result displayed.	Hold down the DIS key and press the MENU soft key.	Utility Menu will be displayed.
Utility Menu 1 Clear Stored Results 2 Printer Setup 3 Send Software 4 Cal Ver 5 Proficiency	Press 5 for Proficiency.	Insert cartridge prompt will be displayed.
Proficiency INSERT CARTRIDGE	Insert filled cartridge into analyzer cartridge port. If the display turns OFF before the cartridge is inserted, turn the analyzer ON using the DIS key. Re-enter the Utility menu and select the Proficiency option before inserting the filled cartridge.	Test cycle will commence. If at any point during the test cycle a quality check fails, the test cycle will halt and a message will be displayed indicating the condition and the corrective action.
#_ _ _ _ _ _ _ Operator #, ENT	Enter Operator ID and press ENT.	
#_ _ _ _ _ _ _ Repeat #, ENT	Repeat Operator ID and press ENT.	Repeat of Operator ID entry may not be required depending on analyzer customization settings. If the repeated ID does not match the original, the ID must be re-entered.
#_ _ _ _ _ _ _ _ _ _ _ _ _ ID, ENT	Enter the sample ID number and press ENT.	

#_____________ Repeat #, ENT	Repeat the sample ID number and press ENT.	Repeat of sample ID entry may not be required depending on analyzer customization settings. If the repeated ID does not match the original, the ID must be re-entered.
Select Tests (Available tests will be dependent on cartridge type).	Use the number keys to select tests to be reported. (Press a number key a second time to deselect a test.) Press PAGE key when all desired tests are selected.	Test selection may not be required depending on analyzer customization settings.
Chart Page	Use the number and ENT keys to enter test information if desired. Press PAGE key when all information entry is complete.	Automatic display of the Chart Page is dependent on analyzer customization settings.
Results Displayed	If results are not displayed, but RESULTS READY message is visible, press the PAGE key until the results page is shown. Remove the cartridge and discard in a biohazard container. Print or transcribe results.	Analyzer unlocks cartridge and is ready for another cartridge. If another cartridge is inserted into the analyzer without pressing DIS and MENU, it will be run as a patient sample. To run another Proficiency sample continue to next instruction.
Results Displayed	To run another Proficiency sample, hold down the DIS key and press the MENU key.	Utility Menu will be displayed.
Utility Menu 1 Cal Ver 2 Proficiency	Press 2 for Proficiency	Insert Cartridge prompt will be displayed. Follow sequence from the Insert Cartridge screen as shown above to complete the test cycle.

Troubleshooting Cartridge Tests

If results are considered unsatisfactory by the provider, consider the following:

- Transcription errors.
- Result reported under wrong method or peer group.
- Matrix effects.
  - › Split sample testing of both the control samples and patient samples can be performed on the i-STAT System and a comparative method. If patient results agree but control samples do not agree, the presence of a matrix effect or interfering substance in the control samples is very likely.
  - › Petition the provider for a peer group for the i-STAT method.
- See also the Control Out-of-Range paragraph in the Routine Care, Troubleshooting & Technical Information section.

i-STAT Level 1 Control
LOT Lot No: B1102
⌛ Exp. Date: 31 OCT 2002

CLEW std: A84*

37°

Crea Lot No: K, M, P, R or T (≤02165)

CG8+, EG7+, EG6+, CG4+ & G3+ Lot No: K, M, P, R or T (01xxx,02xxx)

		Mean	Range
Na	mmol/L, mEq/L	122	118-126
K	mmol/L, mEq/L	2.8	2.4-3.2
*i*Ca	mmol/L	1.48	1.37-1.59
	mg/dL	5.9	5.5-6.3
	mEq/L	3.0	2.8-3.1
pH		7.178	7.128-7.228
$P\mathrm{CO}_2$	mm Hg	65.5	57.5-73.5
	kPa	8.73	7.66-9.80
$P\mathrm{O}_2$	mm Hg	77	62-92
	kPa	10.2	8.2-12.2
Glucose	mg/dL	39	30-48
	g/L	0.39	0.30-0.48
	mmol/L	2.2	1.7-2.6
Creatinine	mg/dL	5.0	4.2-5.8
	umol/L	445	374-515
Lactate	mmol/L	7.98	7.06-8.90
	mg/dL	71.9	63.6-80.2
	g/L	0.719	0.636-0.802

EC8+, EC6+, 6+, EC4+, E3+ & G Lot No: A, B, C, D or E (01xxx,02xxx)

		Mean	Range
Na	mmol/L, mEq/L	122	118-126
K	mmol/L, mEq/L	2.8	2.4-3.2
Cl	mmol/L, mEq/L	78	73-83
*i*Ca	mmol/L	1.56	1.45-1.67
	mg/dL	6.2	5.8-6.7
	mEq/L	3.1	3.0-3.3
pH		7.177	7.127-7.227
$P\mathrm{CO}_2$	mm Hg	65.5	57.5-73.5
	kPa	8.73	7.66-9.80
Glucose	mg/dL	39	30-48
	g/L	0.39	0.30-0.48
	mmol/L	2.2	1.7-2.6
BUN	mg/dL	54	47-61
Urea	mmol/L	19.4	16.9-21.9
	mg/dL	116	101-131
	g/L	1.16	1.01-1.31

*** or equivalent: C84, H84, J84**

See System Manual for instructions/ Anleitungen stehen in der Gebrauchsanweisung des Geraetes/ Pour plus d'informations, se reporter au Manuel Systeme/ Para las instrucciones de uso, consultar el Manual del Sistema/ Leggere le instruzioni nel manuale del sistema/ Raadpleeg de systeamhandleidingvoor aanwijzingen/ Se instruktionema i systemhandleboken.

i-STAT Corporation
East Windsor, NJ 08520
Made in USA.

015045-01
715045-01 A
06/06/02

i-STAT Level 1 Control
LOT Lot No: B1102
Exp. Date: 31 OCT 2002

CLEW std: A84*

37°

Crea Lot No: K, M, P, R or T (≥02166)

CG8+, EG7+, EG6+, CG4+ & G3+ Lot No: K, M, P, R or T (01xxx,02xxx)

		Mean	Range
Na	mmol/L, mEq/L	122	118-126
K	mmol/L, mEq/L	2.8	2.4-3.2
*i*Ca	mmol/L	1.48	1.37-1.59
	mg/dL	5.9	5.5-6.3
	mEq/L	3.0	2.8-3.1
pH		7.178	7.128-7.228
PCO$_2$	mm Hg	65.5	57.5-73.5
	kPa	8.73	7.66-9.80
PO$_2$	mm Hg	77	62-92
	kPa	10.2	8.2-12.2
Glucose	mg/dL	39	30-48
	g/L	0.39	0.30-0.48
	mmol/L	2.2	1.7-2.6
Creatinine	mg/dL	5.5	4.7-6.3
	umol/L	486	415-557
Lactate	mmol/L	7.98	7.06-8.90
	mg/dL	71.9	63.6-80.2
	g/L	0.719	0.636-0.802

EC8+, EC6+, 6+, EC4+, E3+ & G Lot No: A, B, C, D or E (01xxx,02xxx)

		Mean	Range
Na	mmol/L, mEq/L	122	118-126
K	mmol/L, mEq/L	2.8	2.4-3.2
Cl	mmol/L, mEq/L	78	73-83
*i*Ca	mmol/L	1.56	1.45-1.67
	mg/dL	6.2	5.8-6.7
	mEq/L	3.1	3.0-3.3
pH		7.177	7.127-7.227
PCO$_2$	mm Hg	65.5	57.5-73.5
	kPa	8.73	7.66-9.80
Glucose	mg/dL	39	30-48
	g/L	0.39	0.30-0.48
	mmol/L	2.2	1.7-2.6
BUN	mg/dL	54	47-61
Urea	mmol/L	19.4	16.9-21.9
	mg/dL	116	101-131
	g/L	1.16	1.01-1.31

*** or equivalent: C84, H84, J84**

See System Manual for instructions/ Anleitungen stehen in der Gebrauchsanweisung des Geraetes/ Pour plus d'informations, se reporter au Manuel Systeme/ Para las instrucciones de uso, consultar el Manual del Sistema/ Leggere le instruzioni nel manuale del sistema/ Raadpleeg de systeamhandleidingvoor aanwijzingen/ Se instruktionema i systemhandleboken.

i-STAT Corporation
East Windsor, NJ 08520
Made in USA.

015143-01
715143-01 A
06/06/02

i-STAT Level 2 Control
LOT Lot No: B1094
⌛ Exp. Date: 31 OCT 2002

CLEW std: A84*

37°

Crea Lot No: K, M, P, R or T (≤02165)
CG8+, EG7+, EG6+, CG4+ & G3+ Lot No: K, M, P, R or T (01xxx,02xxx)

		Mean	Range
Na	mmol/L, mEq/L	136	132-140
K	mmol/L, mEq/L	3.7	3.3-4.1
*i*Ca	mmol/L	1.23	1.15-1.31
	mg/dL	4.9	4.6-5.2
	mEq/L	2.5	2.3-2.6
pH		7.463	7.413-7.513
$P\mathrm{CO}_2$	mm Hg	27.9	20.9-34.9
	kPa	3.72	2.79-4.66
$P\mathrm{O}_2$	mm Hg	108	93-123
	kPa	14.4	12.4-16.4
Glucose	mg/dL	123	109-137
	g/L	1.23	1.09-1.37
	mmol/L	6.8	6.0-7.6
Creatinine	mg/dL	2.3	1.9-2.7
	umol/L	202	166-237
Lactate	mmol/L	2.09	1.59-2.59
	mg/dL	18.8	14.3-23.3
	g/L	0.188	0.143-0.233

EC8+, EC6+, 6+, EC4+, E3+ & G Lot No: A, B, C, D or E (01xxx,02xxx)

		Mean	Range
Na	mmol/L, mEq/L	136	132-140
K	mmol/L, mEq/L	3.7	3.3-4.1
Cl	mmol/L, mEq/L	92	87-97
*i*Ca	mmol/L	1.30	1.22-1.38
	mg/dL	5.2	4.9-5.5
	mEq/L	2.6	2.4-2.8
pH		7.461	7.411-7.511
$P\mathrm{CO}_2$	mm Hg	26.6	19.6-33.6
	kPa	3.54	2.61-4.47
Glucose	mg/dL	123	109-137
	g/L	1.23	1.09-1.37
	mmol/L	6.8	6.0-7.6
BUN	mg/dL	11	8-14
Urea	mmol/L	3.9	2.9-5.0
	mg/dL	24	17-30
	g/L	0.24	0.17-0.30

*** or equivalent: C84, H84, J84**

See System Manual for instructions/ Anleitungen stehen in der Gebrauchsanweisung des Geraetes/ Pour plus d'informations, se reporter au Manuel Systeme/ Para las instrucciones de uso, consultar el Manual del Sistema/ Leggere le instruzioni nel manuale del sistema/ Raadpleeg de systeamhandleidingvoor aanwijzingen/ Se instruktionerna i systemhandleboken.

i-STAT Corporation
East Windsor, NJ 08520
Made in USA.

015046-01
715046-01 A
06/06/02

i-STAT Level 2 Control
LOT Lot No: B1094
Exp. Date: 31 OCT 2002

CLEW std: A84*

37°

Crea Lot No: K, M, P, R or T (≥02166)
CG8+, EG7+, EG6+, CG4+ & G3+ Lot No: K, M, P, R or T (01xxx,02xxx)

		Mean	**Range**
Na	mmol/L, mEq/L	136	132-140
K	mmol/L, mEq/L	3.7	3.3-4.1
*i*Ca	mmol/L	1.23	1.15-1.31
	mg/dL	4.9	4.6-5.2
	mEq/L	2.5	2.3-2.6
pH		7.463	7.413-7.513
PCO_2	mm Hg	27.9	20.9-34.9
	kPa	3.72	2.79-4.66
PO_2	mm Hg	108	93-123
	kPa	14.4	12.4-16.4
Glucose	mg/dL	123	109-137
	g/L	1.23	1.09-1.37
	mmol/L	6.8	6.0-7.6
Creatinine	mg/dL	2.5	2.1-2.9
	umol/L	221	185-256
Lactate	mmol/L	2.09	1.59-2.59
	mg/dL	18.8	14.3-23.3
	g/L	0.188	0.143-0.233

EC8+, EC6+, 6+, EC4+, E3+ & G Lot No: A, B, C, D or E (01xxx,02xxx)

		Mean	**Range**
Na	mmol/L, mEq/L	136	132-140
K	mmol/L, mEq/L	3.7	3.3-4.1
Cl	mmol/L, mEq/L	92	87-97
*i*Ca	mmol/L	1.30	1.22-1.38
	mg/dL	5.2	4.9-5.5
	mEq/L	2.6	2.4-2.8
pH		7.461	7.411-7.511
PCO_2	mm Hg	26.6	19.6-33.6
	kPa	3.54	2.61-4.47
Glucose	mg/dL	123	109-137
	g/L	1.23	1.09-1.37
	mmol/L	6.8	6.0-7.6
BUN	mg/dL	11	8-14
Urea	mmol/L	3.9	2.9-5.0
	mg/dL	24	17-30
	g/L	0.24	0.17-0.30

*** or equivalent: C84, H84, J84**

See System Manual for instructions/ Anleitungen stehen in der Gebrauchsanweisung des Geraetes/ Pour plus d'informations, se reporter au Manuel Systeme/ Para las instrucciones de uso, consultar el Manual del Sistema/ Leggere le instruzioni nel manuale del sistema/ Raadpleeg de systeamhandleidingvoor aanwijzingen/ Se instruktionerna i systemhandleboken.

i-STAT Corporation
East Windsor, NJ 08520
Made in USA.

015144-01
715144-01 A
06/06/02

i-STAT Level 2 Control
LOT Lot No: B1019
⌛ Exp. Date: 31 JUL 2002

CLEW std: A84*

37°

Crea Lot No: K, M, P, R or T (≤02165)
CG8+, EG7+, EG6+, CG4+ & G3+ Lot No: K, M, P, R or T (01xxx,02xxx)

		Mean	Range
Na	mmol/L, mEq/L	136	132-140
K	mmol/L, mEq/L	3.7	3.3-4.1
*i*Ca	mmol/L	1.22	1.14-1.30
	mg/dL	4.9	4.5-5.2
	mEq/L	2.4	2.3-2.6
pH		7.470	7.420-7.520
PCO_2	mm Hg	27.3	20.3-34.3
	kPa	3.63	2.70-4.57
PO_2	mm Hg	107	92-122
	kPa	14.3	12.3-16.3
Glucose	mg/dL	123	109-137
	g/L	1.23	1.09-1.37
	mmol/L	6.8	6.1-7.6
Creatinine	mg/dL	2.6	2.2-3.0
	umol/L	232	197-268
Lactate	mmol/L	2.13	1.63-2.63
	mg/dL	19.2	14.7-23.7
	g/L	0.192	0.147-0.237

EC8+, EC6+, 6+, EC4+, E3+ & G Lot No: A, B, C, D or E (01xxx,02xxx)

		Mean	Range
Na	mmol/L, mEq/L	137	133-141
K	mmol/L, mEq/L	3.7	3.3-4.1
Cl	mmol/L, mEq/L	92	87-97
*i*Ca	mmol/L	1.30	1.22-1.38
	mg/dL	5.2	4.9-5.5
	mEq/L	2.6	2.4-2.8
pH		7.471	7.421-7.521
PCO_2	mm Hg	26.7	19.7-33.7
	kPa	3.56	2.63-4.49
Glucose	mg/dL	123	109-137
	g/L	1.23	1.09-1.37
	mmol/L	6.8	6.1-7.6
BUN	mg/dL	11	8-14
Urea	mmol/L	4.0	2.9-5.1
	mg/dL	24	18-31
	g/L	0.24	0.18-0.31

*** or equivalent: C84, H84, J84**

See System Manual for instructions/ Anleitungen stehen in der Gebrauchsanweisung des Geraetes/ Pour plus d'informations, se reporter au Manuel Systeme/ Para las instrucciones de uso, consultar el Manual del Sistema/ Leggere le instruzioni nel manuale del sistema/ Raadpleeg de systeemhandleidingvoor aanwijzingen/ Se instruktionerna i systemhandleboken.

i-STAT Corporation
East Windsor, NJ 08520
Made in USA.

015047-01
715047-01 A
06/06/02

i-STAT Level 2 Control
LOT Lot No: B1019
Exp. Date: 31 JUL 2002

CLEW std: A84*

37°

Crea Lot No: K, M, P, R or T (≥02166)
CG8+, EG7+, EG6+, CG4+ & G3+ Lot No: K, M, P, R or T (01xxx,02xxx)

		Mean	**Range**
Na	mmol/L, mEq/L	136	132-140
K	mmol/L, mEq/L	3.7	3.3-4.1
*i*Ca	mmol/L	1.22	1.14-1.30
	mg/dL	4.9	4.5-5.2
	mEq/L	2.4	2.3-2.6
pH		7.470	7.420-7.520
$\boldsymbol{P}CO_2$	mm Hg	27.3	20.3-34.3
	kPa	3.63	2.70-4.57
$\boldsymbol{P}O_2$	mm Hg	107	92-122
	kPa	14.3	12.3-16.3
Glucose	mg/dL	123	109-137
	g/L	1.23	1.09-1.37
	mmol/L	6.8	6.1-7.6
Creatinine	mg/dL	2.8	2.4-3.2
	umol/L	248	212-283
Lactate	mmol/L	2.13	1.63-2.63
	mg/dL	19.2	14.7-23.7
	g/L	0.192	0.147-0.237

EC8+, EC6+, 6+, EC4+, E3+ & G Lot No: A, B, C, D or E (01xxx,02xxx)

		Mean	**Range**
Na	mmol/L, mEq/L	137	133-141
K	mmol/L, mEq/L	3.7	3.3-4.1
Cl	mmol/L, mEq/L	92	87-97
*i*Ca	mmol/L	1.30	1.22-1.38
	mg/dL	5.2	4.9-5.5
	mEq/L	2.6	2.4-2.8
pH		7.471	7.421-7.521
$\boldsymbol{P}CO_2$	mm Hg	26.7	19.7-33.7
	kPa	3.56	2.63-4.49
Glucose	mg/dL	123	109-137
	g/L	1.23	1.09-1.37
	mmol/L	6.8	6.1-7.6
BUN	mg/dL	11	8-14
Urea	mmol/L	4.0	2.9-5.1
	mg/dL	24	18-31
	g/L	0.24	0.18-0.31

*** or equivalent: C84, H84, J84**

See System Manual for instructions/ Anleitungen stehen in der Gebrauchsanweisung des Geraetes/ Pour plus d'informations, se reporter au Manuel Systeme/ Para las instrucciones de uso, consultar el Manual del Sistema/ Leggere le instruzioni nel manuale del sistema/ Raadpleeg de systeamhandleidingvoor aanwijzingen/ Se instruktionerna i systemhandleboken.

I-STAT Corporation
East Windsor, NJ 08520
Made in USA.

015145-01
715145-01 A
06/06/02

i-STAT Level 3 Control
LOT Lot No: B1108
Exp. Date: 31 OCT 2002

CLEW std: A84*

37°

Crea Lot No: K, M, P, R or T (≤02165)
CG8+, EG7+, EG6+, CG4+ & G3+ Lot No: K, M, P, R or T (01xxx,02xxx)

		Mean	Range
Na	mmol/L, mEq/L	161	156-166
K	mmol/L, mEq/L	6.4	5.9-6.9
*i*Ca	mmol/L	0.79	0.71-0.87
	mg/dL	3.2	2.8-3.5
	mEq/L	1.6	1.4-1.7
pH		7.692	7.642-7.742
PCO_2	mm Hg	20.0	14.0-26.0
	kPa	2.67	1.87-3.47
PO_2	mm Hg	145	127-163
	kPa	19.3	16.9-21.7
Glucose	mg/dL	289	247-331
	g/L	2.89	2.47-3.31
	mmol/L	16.1	13.7-18.4
Creatinine	mg/dL	1.0	0.6-1.4
	umol/L	84	49-119
Lactate	mmol/L	0.81	0.31-1.31
	mg/dL	7.3	2.8-11.8
	g/L	0.073	0.028-0.118

EC8+, EC6+, 6+, EC4+, E3+ & G Lot No: A, B, C, D or E (01xxx,02xxx)

		Mean	Range
Na	mmol/L, mEq/L	161	156-166
K	mmol/L, mEq/L	6.4	5.9-6.9
Cl	mmol/L, mEq/L	115	109-121
*i*Ca	mmol/L	0.84	0.76-0.92
	mg/dL	3.4	3.1-3.7
	mEq/L	1.7	1.5-1.8
pH		7.689	7.639-7.739
PCO_2	mm Hg	19.0	13.0-25.0
	kPa	2.53	1.73-3.33
Glucose	mg/dL	289	247-331
	g/L	2.89	2.47-3.31
	mmol/L	16.1	13.7-18.4
BUN	mg/dL	6	4-8
Urea	mmol/L	2.1	1.4-2.8
	mg/dL	12	8-17
	g/L	0.12	0.08-0.17

*** or equivalent: C84, H84, J84**

See System Manual for instructions/ Anleitungen stehen in der Gebrauchsanweisung des Geraetes/ Pour plus d'informations, se reporter au Manuel Systeme/ Para las instrucciones de uso, consultar el Manual del Sistema/ Leggere le instruzioni nel manuale del sistema/ Raadpleeg de systeamhandleidingvoor aanwijzingen/ Se instruktionerna i systemhandleboken.

i-STAT Corporation
East Windsor, NJ 08520
Made in USA.

015048-01
715048-01 A
06/06/02

i-STAT Level 3 Control
LOT Lot No: B1108
Exp. Date: 31 OCT 2002

CLEW std: A84*

37°

Crea Lot No: K, M, P, R or T (≥02166)

CG8+, EG7+, EG6+, CG4+ & G3+ Lot No: K, M, P, R or T (01xxx,02xxx)

		Mean	Range
Na	mmol/L, mEq/L	161	156-166
K	mmol/L, mEq/L	6.4	5.9-6.9
*i*Ca	mmol/L	0.79	0.71-0.87
	mg/dL	3.2	2.8-3.5
	mEq/L	1.6	1.4-1.7
pH		7.692	7.642-7.742
$P\mathrm{CO}_2$	mm Hg	20.0	14.0-26.0
	kPa	2.67	1.87-3.47
$P\mathrm{O}_2$	mm Hg	145	127-163
	kPa	19.3	16.9-21.7
Glucose	mg/dL	289	247-331
	g/L	2.89	2.47-3.31
	mmol/L	16.1	13.7-18.4
Creatinine	mg/dL	1.1	0.7-1.5
	umol/L	97	62-133
Lactate	mmol/L	0.81	0.31-1.31
	mg/dL	7.3	2.8-11.8
	g/L	0.073	0.028-0.118

EC8+, EC6+, 6+, EC4+, E3+ & G Lot No: A, B, C, D or E (01xxx,02xxx)

		Mean	Range
Na	mmol/L, mEq/L	161	156-166
K	mmol/L, mEq/L	6.4	5.9-6.9
Cl	mmol/L, mEq/L	115	109-121
*i*Ca	mmol/L	0.84	0.76-0.92
	mg/dL	3.4	3.1-3.7
	mEq/L	1.7	1.5-1.8
pH		7.689	7.639-7.739
$P\mathrm{CO}_2$	mm Hg	19.0	13.0-25.0
	kPa	2.53	1.73-3.33
Glucose	mg/dL	289	247-331
	g/L	2.89	2.47-3.31
	mmol/L	16.1	13.7-18.4
BUN	mg/dL	6	4-8
Urea	mmol/L	2.1	1.4-2.8
	mg/dL	12	8-17
	g/L	0.12	0.08-0.17

*** or equivalent: C84, H84, J84**

See System Manual for instructions/ Anleitungen stehen in der Gebrauchsanweisung des Geraetes/ Pour plus d'informations, se reporter au Manuel Systeme/ Para las instrucciones de uso, consultar el Manual del Sistema/ Leggere le instruzioni nel manuale del sistema/ Raadpleeg de systeamhandleidingvoor aanwijzingen/ Se instruktionema i systemhandleboken.

i-STAT Corporation
East Windsor, NJ 08520
Made in USA.

015146-01
715146-01 A
06/06/02

i-STAT Calibration Verification Set
LOT Lot No: L1 B1109, L2 B1102, L3 B1094, L4 B1108, L5 B1101
Exp. Date: 31 OCT 2002

CLEW std: A84*

37°
Crea Lot No: K, M, P, R or T (≤02165)
CG8+, EG7+, EG6+, CG4+ & G3+ Lot No: K, M, P, R or T (01xxx,02xxx)

		1	2	3	4	5
Na	mmol/L	104.3	122.0	136.0	161.0	179.0
	mEq/L	100.9-107.7	118.6-125.4	132.1-139.9	156.6-165.4	173.8-184.2
K	mmol/L	2.05	2.85	3.72	6.40	8.03
	mEq/L	1.78-2.31	2.58-3.11	3.43-4.01	6.01-6.79	7.53-8.53
pH		6.825	7.178	7.463	7.692	8.098
		6.776-6.874	7.129-7.227	7.414-7.512	7.643-7.741	8.049-8.147
***P*CO$_2$**	mmHg	91.33	65.50	27.94	20.03	15.85
		82.38-100.28	59.08-71.92	22.55-33.33	14.89-25.17	10.95-20.75
	kPa	12.174	8.731	3.724	2.670	2.113
		10.981-13.367	7.876-9.587	3.006-4.443	1.984-3.356	1.460-2.766
***P*O2**	mmHg	61.5	76.5	108.0	144.8	400.0
		48.5-74.5	63.5-89.5	94.0-122.0	126.0-163.5	348.2-451.8
	kPa	8.20	10.20	14.40	19.30	53.32
		6.47-9.93	8.47-11.93	12.53-16.26	16.79-21.80	46.41-60.23
***i*Ca**	mmol/L	2.185	1.475	1.225	0.790	0.330
		2.055-2.315	1.383-1.567	1.149-1.301	0.725-0.855	0.273-0.387
	mg/dL	8.74	5.90	4.90	3.16	1.32
		8.22-9.26	5.53-6.27	4.60-5.20	2.90-3.42	1.09-1.55
	mEq/L	4.37	2.95	2.45	1.58	0.66
		4.11-4.63	2.77-3.13	2.30-2.60	1.45-1.71	0.55-0.77
Glucose	mg/dL	26.5	39.2	122.7	289.3	608.1
		17.3-35.6	32.4-46.0	110.2-135.3	259.8-318.9	539.0-677.1
	g/L	0.265	0.392	1.227	2.893	6.081
		0.173-0.356	0.324-0.460	1.102-1.353	2.598-3.189	5.390-6.771
	mmol/L	1.47	2.18	6.81	16.06	33.75
		0.96-1.98	1.80-2.56	6.12-7.51	14.42-17.70	29.92-37.58
Creatinine	mg/dL	16.50	5.03	2.28	0.95	0.75
		13.55-19.45	4.40-5.66	1.92-2.64	0.59-1.31	0.39-1.11
	umol/L	1458.6	444.7	201.6	84.0	66.3
		1197.4-1719.8	388.9-500.4	169.9-233.2	52.3-115.6	34.6-98.0
Lactate	mmol/L	17.422	7.982	2.085	0.809	0.418
		14.86-19.98	7.10-8.86	1.68-2.49	0.40-1.22	0.01-0.83
	mg/dL	157.0	71.9	18.79	7.29	3.77
		133.9-180.0	64.0-79.8	15.1-22.5	3.6-11.0	0.1-7.4
	g/L	1.570	0.719	0.1879	0.0729	0.0377
		1.339-1.800	0.640-0.798	0.151-0.225	0.036-0.110	0.001-0.074

*** or equivalent: C84, H84, J84**

See System Manual for instructions/ Anleitungen stehen in der Gebrauchsanweisung des Geraetes/ Pour plus d'informations,se reporter au Manuel Systeme/ Para las instrucciones de uso, consultar el Manual del Sistema/ Leggere le instruzioni nel manuale del sistema/Raadpleeg de systeamhandleidingvoor aanwijzingen/ Se instruktionerna i systemhandleboken.

i-STAT Corporation
East Windsor, NJ 08520
Made in USA.

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i-STAT Calibration Verification Set
LOT Lot No: L1 B1109, L2 B1102, L3 B1094, L4 B1108, L5 B1101
Exp. Date: 31 OCT 2002

CLEW std: A84*

EC8+, EC6+, 6+, EC4+, E3+ & G Lot No: A, B, C, D or E (01xxx,02xxx)

		1	2	3	4	5
Na	mmol/L	103.5	122.5	136.0	160.6	178.2
	mEq/L	100.1-106.9	119.1-125.8	132.1-139.9	156.2-165.0	173.0-183.4
K	mmol/L	2.07	2.80	3.71	6.40	8.00
	mEq/L	1.81-2.33	2.54-3.06	3.42-4.00	6.01-6.79	7.50-8.50
Cl	mmol/L	66.4	77.9	91.6	115.0	125.5
	mEq/L	62.4-70.4	73.6-82.1	87.1-96.1	109.0-121.0	118.0-133.0
pH		6.828	7.177	7.461	7.689	8.077
		6.779-6.877	7.128-7.226	7.412-7.510	7.640-7.738	8.028-8.126
***P*CO$_2$**	mmHg	95.19	65.49	26.56	18.98	14.63
		85.86-104.52	59.07-71.91	21.17-31.95	13.84-24.12	9.73-19.53
	kPa	12.689	8.730	3.540	2.530	1.950
		11.446-13.932	7.874-9.585	2.822-4.259	1.844-3.216	1.297-2.603
***i*Ca**	mmol/L	2.300	1.560	1.304	0.843	0.380
		2.170-2.430	1.463-1.657	1.223-1.385	0.778-0.908	0.323-0.437
	mg/dL	9.20	6.24	5.22	3.37	1.52
		8.68-9.72	5.85-6.63	4.89-5.54	3.11-3.63	1.29-1.75
	mEq/L	4.60	3.12	2.61	1.69	0.76
		4.34-4.86	2.93-3.31	2.45-2.77	1.56-1.82	0.65-0.87
Glucose	mg/dL	26.5	39.2	122.7	289.3	608.1
		17.3-35.6	32.4-46.0	110.2-135.3	259.8-318.9	539.0-677.1
	g/L	0.265	0.392	1.227	2.893	6.081
		0.173-0.356	0.324-0.460	1.102-1.353	2.598-3.189	5.390-6.771
	mmol/L	1.47	2.18	6.81	16.06	33.75
		0.96-1.98	1.80-2.56	6.12-7.51	14.42-17.70	29.92-37.58
BUN	mg/dL	143.5	54.4	11.1	5.8	2.3
		125.4-161.5	48.0-60.8	8.4-13.7	3.7-7.9	0.1-4.4
Urea	mmol/L	51.21	19.42	3.95	2.07	0.80
		44.75-57.67	17.13-21.72	3.01-4.89	1.32-2.82	0.05-1.55
	mg/dL	307.0	116.4	23.7	12.4	4.8
		268.3-345.7	102.7-130.2	18.0-29.3	7.9-16.9	0.3-9.3
	g/L	3.070	1.164	0.237	0.124	0.048
		2.683-3.457	1.027-1.302	0.180-0.293	0.079-0.169	0.003-0.093

*** or equivalent: C84, H84, J84**

015044-01
715044-01 A
06/06/02

i-STAT Calibration Verification Set
LOT Lot No: L1 B1109, L2 B1102, L3 B1094, L4 B1108, L5 B1101
Exp. Date: 31 OCT 2002

CLEW std: A84*

37°

Crea Lot No: K, M, P, R or T (≥02166)
CG8+, EG7+, EG6+, CG4+ & G3+ Lot No: K, M, P, R or T (01xxx,02xxx)

		1	2	3	4	5
Na	mmol/L	104.3	122.0	136.0	161.0	179.0
	mEq/L	100.9-107.7	118.6-125.4	132.1-139.9	156.6-165.4	173.8-184.2
K	mmol/L	2.05	2.85	3.72	6.40	8.03
	mEq/L	1.78-2.31	2.58-3.11	3.43-4.01	6.01-6.79	7.53-8.53
pH		6.825	7.178	7.463	7.692	8.098
		6.776-6.874	7.129-7.227	7.414-7.512	7.643-7.741	8.049-8.147
***P*CO$_2$**	mmHg	91.33	65.50	27.94	20.03	15.85
		82.38-100.28	59.08-71.92	22.55-33.33	14.89-25.17	10.95-20.75
	kPa	12.174	8.731	3.724	2.670	2.113
		10.981-13.367	7.876-9.587	3.006-4.443	1.984-3.356	1.460-2.766
***P*O2**	mmHg	61.5	76.5	108.0	144.8	400.0
		48.5-74.5	63.5-89.5	94.0-122.0	126.0-163.5	348.2-451.8
	kPa	8.20	10.20	14.40	19.30	53.32
		6.47-9.93	8.47-11.93	12.53-16.26	16.79-21.80	46.41-60.23
***i*Ca**	mmol/L	2.185	1.475	1.225	0.790	0.330
		2.055-2.315	1.383-1.567	1.149-1.301	0.725-0.855	0.273-0.387
	mg/dL	8.74	5.90	4.90	3.16	1.32
		8.22-9.26	5.53-6.27	4.60-5.20	2.90-3.42	1.09-1.55
	mEq/L	4.37	2.95	2.45	1.58	0.66
		4.11-4.63	2.77-3.13	2.30-2.60	1.45-1.71	0.55-0.77
Glucose	mg/dL	26.5	39.2	122.7	289.3	608.1
		17.3-35.6	32.4-46.0	110.2-135.3	259.8-318.9	539.0-677.1
	g/L	0.265	0.392	1.227	2.893	6.081
		0.173-0.356	0.324-0.460	1.102-1.353	2.598-3.189	5.390-6.771
	mmol/L	1.47	2.18	6.81	16.06	33.75
		0.96-1.98	1.80-2.56	6.12-7.51	14.42-17.70	29.92-37.58
Creatinine	mg/dL	17.50	5.51	2.50	1.10	0.95
		14.37-20.63	4.82-6.20	2.14-2.85	0.74-1.46	0.59-1.31
	umol/L	1547.0	487.1	220.6	97.2	84.0
		1270.0-1824.0	426.0-548.1	188.9-252.2	65.6-128.9	52.3-115.6
Lactate	mmol/L	17.422	7.982	2.085	0.809	0.418
		14.86-19.98	7.10-8.86	1.68-2.49	0.40-1.22	0.01-0.83
	mg/dL	157.0	71.9	18.79	7.29	3.77
		133.9-180.0	64.0-79.8	15.1-22.5	3.6-11.0	0.1-7.4
	g/L	1.570	0.719	0.1879	0.0729	0.0377
		1.339-1.800	0.640-0.798	0.151-0.225	0.036-0.110	0.001-0.074

*** or equivalent: C84, H84, J84**

See System Manual for instructions/ Anleitungen stehen in der Gebrauchsanweisung des Geraetes/ Pour plus d'informations,se reporter au Manuel Systeme/ Para las instrucciones de uso, consultar el Manual del Sistema/ Leggere le instruzioni nel manuale del sistema/Raadpleeg de systeamhandleidingvoor aanwijzingen/ Se instruktionerna i systemhandleboken.

i-STAT Corporation
East Windsor, NJ 08520
Made in USA.

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i-STAT Calibration Verification Set
LOT Lot No: L1 B1109, L2 B1102, L3 B1094, L4 B1108, L5 B1101
Exp. Date: 31 OCT 2002

CLEW std: A84*

EC8+, EC6+, 6+, EC4+, E3+ & G Lot No: A, B, C, D or E (01xxx,02xxx)

		1	2	3	4	5
Na	mmol/L	103.5	122.5	136.0	160.6	178.2
	mEq/L	100.1-106.9	119.1-125.8	132.1-139.9	156.2-165.0	173.0-183.4
K	mmol/L	2.07	2.80	3.71	6.40	8.00
	mEq/L	1.81-2.33	2.54-3.06	3.42-4.00	6.01-6.79	7.50-8.50
Cl	mmol/L	66.4	77.9	91.6	115.0	125.5
	mEq/L	62.4-70.4	73.6-82.1	87.1-96.1	109.0-121.0	118.0-133.0
pH		6.828	7.177	7.461	7.689	8.077
		6.779-6.877	7.128-7.226	7.412-7.510	7.640-7.738	8.028-8.126
***P*CO$_2$**	mmHg	95.19	65.49	26.56	18.98	14.63
		85.86-104.52	59.07-71.91	21.17-31.95	13.84-24.12	9.73-19.53
	kPa	12.689	8.730	3.540	2.530	1.950
		11.446-13.932	7.874-9.585	2.822-4.259	1.844-3.216	1.297-2.603
***i*Ca**	mmol/L	2.300	1.560	1.304	0.843	0.380
		2.170-2.430	1.463-1.657	1.223-1.385	0.778-0.908	0.323-0.437
	mg/dL	9.20	6.24	5.22	3.37	1.52
		8.68-9.72	5.85-6.63	4.89-5.54	3.11-3.63	1.29-1.75
	mEq/L	4.60	3.12	2.61	1.69	0.76
		4.34-4.86	2.93-3.31	2.45-2.77	1.56-1.82	0.65-0.87
Glucose	mg/dL	26.5	39.2	122.7	289.3	608.1
		17.3-35.6	32.4-46.0	110.2-135.3	259.8-318.9	539.0-677.1
	g/L	0.265	0.392	1.227	2.893	6.081
		0.173-0.356	0.324-0.460	1.102-1.353	2.598-3.189	5.390-6.771
	mmol/L	1.47	2.18	6.81	16.06	33.75
		0.96-1.98	1.80-2.56	6.12-7.51	14.42-17.70	29.92-37.58
BUN	mg/dL	143.5	54.4	11.1	5.8	2.3
		125.4-161.5	48.0-60.8	8.4-13.7	3.7-7.9	0.1-4.4
Urea	mmol/L	51.21	19.42	3.95	2.07	0.80
		44.75-57.67	17.13-21.72	3.01-4.89	1.32-2.82	0.05-1.55
	mg/dL	307.0	116.4	23.7	12.4	4.8
		268.3-345.7	102.7-130.2	18.0-29.3	7.9-16.9	0.3-9.3
	g/L	3.070	1.164	0.237	0.124	0.048
		2.683-3.457	1.027-1.302	0.180-0.293	0.079-0.169	0.003-0.093

*** or equivalent: C84, H84, J84**

i-STAT ACT Level 1 Control
LOT Lot No. B01276
⌛ Exp. Date: 31 January 2003

CLEW std: A84*

37°

Celite ACT Lot No: K,M,P,R or T (01xxx,02xxx)

		Mean	**Range**
ACT (WBT)	sec	175	123-228

*** or equivalent: C84, H84, J84**

See System Manual for instructions/ Anleitungen stehen in der Gebrauchsanweisung des Geraetes/ Pour plus d'informations, se reporter au Manuel Systeme/ Para las instrucciones de uso, consultar el Manual del Sistema/ Leggere le instruzioni nel manuale del sistema/ Raadpleeg de systeamhandleidingvoor aanwijzingen/ Se instruktionerna i systemhandleboken.

i-STAT Corporation
East Windsor, NJ 08520
Made in USA.

015049-01
715049-01 A
06/06/02

i-STAT ACT Level 2 Control
LOT Lot No. B02003
Exp. Date: 30 APR 2003

CLEW std: A84*

37°

Celite ACT Lot No: K,M,P,R or T (01xxx,02xxx)

		Mean	Range
ACT (WBT)	sec	500	350-650

*** or equivalent: C84, H84, J84**

See System Manual for instructions/ Anleitungen stehen in der Gebrauchsanweisung des Geraetes/ Pour plus d'informations, se reporter au Manuel Systeme/ Para las instrucciones de uso, consultar el Manual del Sistema/ Leggere le instruzioni nel manuale del sistema/ Raadpleeg de systeamhandleidingvoor aanwijzingen/ Se instruktionerna i systemhandleboken.

i-STAT Corporation
East Windsor, NJ 08520
Made in USA.